

Chapter 5

CHEMICAL, PHYSICAL AND ECONOMICALLY MOTIVATED FOOD SAFETY HAZARDS FOR HUMAN FOOD

Chemical, Physical and Economically Motivated Food Safety Hazards Objectives

In this module you will develop awareness of:

- Chemical (including radiological) food safety hazards
- Physical food safety hazards
- Economically motivated food safety hazards
- Potential controls for these hazards

“Hazard” Does Not Necessarily Refer To:

- Violations of regulatory standards not directly related to food safety, e.g.:
 - Economic fraud*
 - Standards of identity
- Undesirable conditions that generally are not hazards requiring a preventive control, e.g.:
 - Spoilage*
 - Insect fragments
 - Hair
 - Filth
- The above may be subject to other regulatory requirements

* Unless associated with a specific safety issue

Chemical Hazards – General

- Chemicals occurring naturally
- Chemicals used in formulation
- Chemicals unintentionally or incidentally present

Chemical Hazards Health Effects

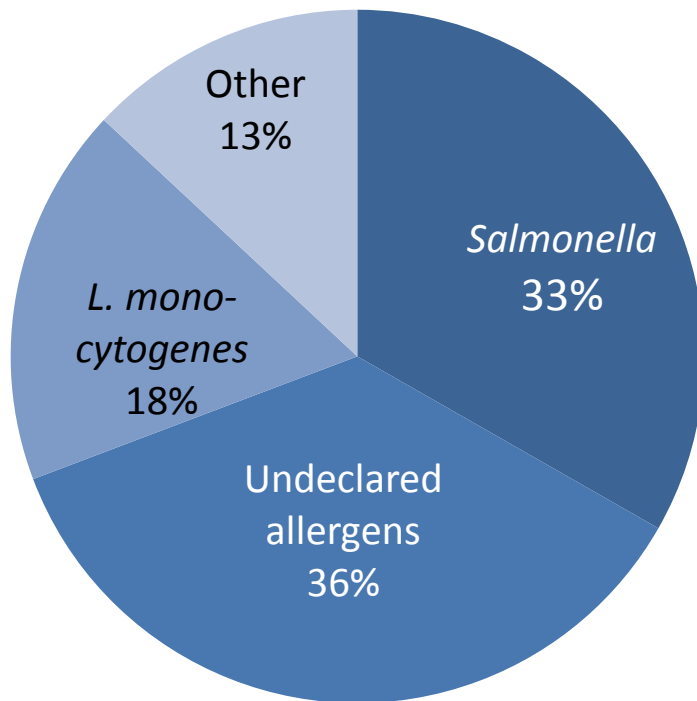
- Depend on the chemical and level in food
- Some may cause immediate or near-term illness, e.g.,
 - Undeclared food allergens → allergic reaction
 - Caustic cleaning compounds → tissue injury
- Some may cause long-term effects, e.g.,
 - Lead in candy → impaired cognitive development in children
 - Chronic aflatoxin exposure → liver cancer
- FDA evaluates long-term and short-term exposure risks to establish specific food chemical use policy

Chemical Hazards Examples

- Naturally occurring
 - Food allergens, mycotoxins, decomposition by-products
- Used in formulation
 - Food additives, color additives, preservatives
- Unintentionally or incidentally present
 - Cleaning and sanitizing chemicals, pesticides, industrial chemicals, heavy metals, drug residues, radiological hazards

Undeclared Food Allergens Commonly Reported

Reportable Food Registry Reports 2009-2013



- Undeclared allergens represent about 1/3 of RFR reports.

www.fda.gov/ReportableFoodRegistry

Food Allergy

- An adverse response by the body to foods containing allergenic proteins
- A miniscule amount of protein/allergen can trigger different symptoms in different individuals
- Food allergy symptoms are unpredictable and vary from mild reactions to death

Food Allergy Symptoms

- Mouth: swelling and tingling of lips, mouth or tongue
- GI: cramping, vomiting, diarrhea
- Skin: hives, eczema
- Airway: wheezing, coughing, swelling of throat
- Cardiovascular: loss of blood pressure
- Anaphylaxis: most dangerous, life threatening

EXERCISE

- Raise your hand if you have a food allergy, or if have a family member or close friend with one?
- Feel free to share with the class what you have to do to deal with this.

Major Food Allergens (The Big 8)

- Milk
- Egg
- Peanut
- Tree nuts
- Fish
- Crustacean Shellfish
- Wheat
- Soy



90% of food allergic reactions are caused by these allergens

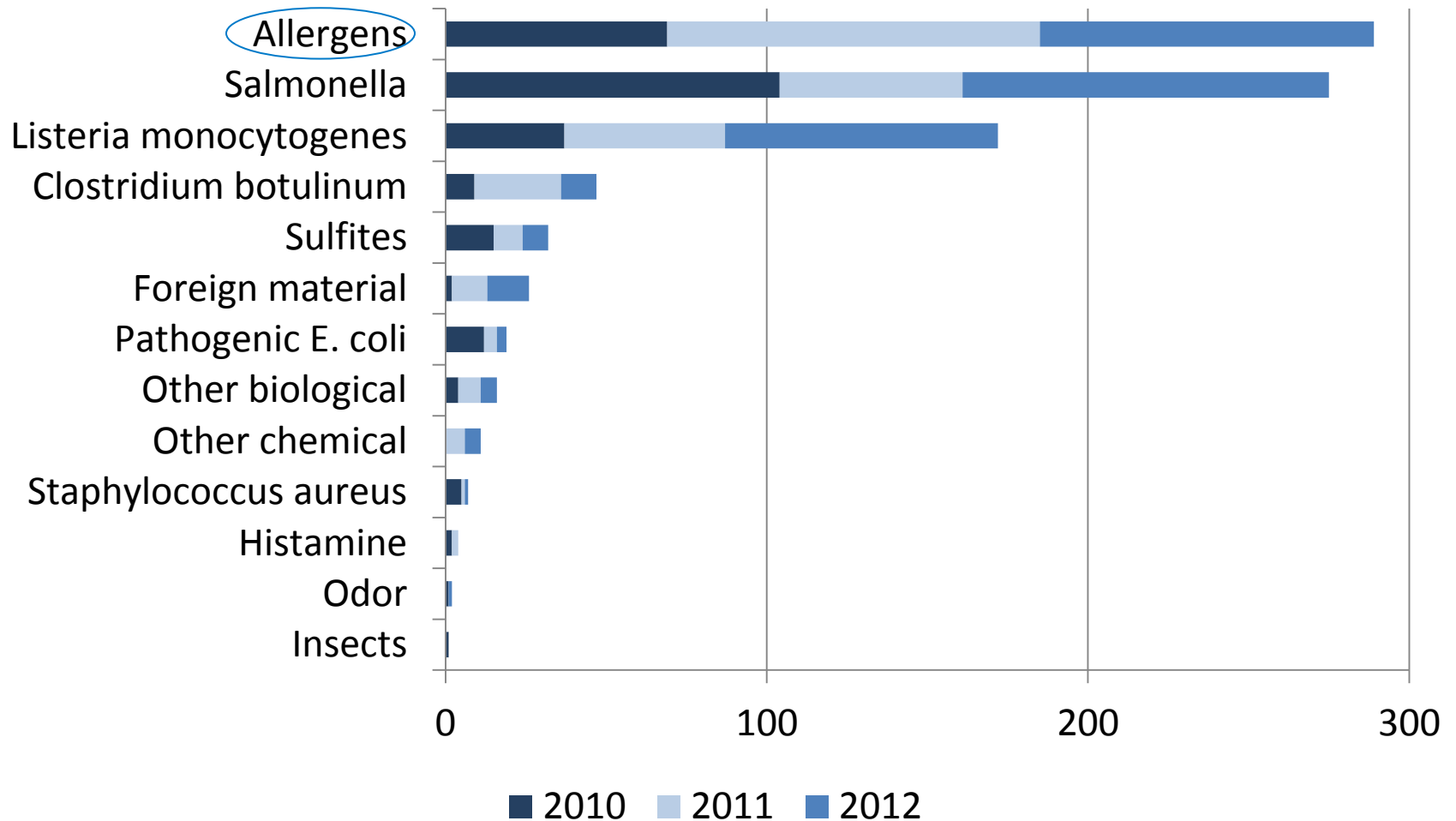


Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

Avoidance is the Primary Treatment

- Complete avoidance of the allergen is the primary treatment for food allergies
- This requires:
 - Individual responsibility to avoid and prepare for accidental exposure
 - Those supplying or preparing food to provide accurate information and safe food

FDA Food Recalls (2010-12)



Adapted from: FDA 2010 Recalls, Market Withdrawals and Safety Alerts

Known Causes of Allergen Recalls

Most Common

	Number
Wrong label or package	137
Terminology not correct	85
No carry-through of info from ingredient	70
Cross-contact	52
Wrong ingredient	31
Rework	9

Other

	Number
Knowledge	28
Ingredient mislabeled	26
Not updated after formula change	22
Computer error	21
In process	19
Other	14
No declaration	12

Adapted from Gendel and Zhu 2013

Allergens in Product Design

- Understand existing allergen profile of the line or facility
- Minimize introduction of unique allergens in product formulation
- Work with ingredient suppliers to remove unnecessary allergens
- Avoid use of allergenic minor ingredients

Mycotoxins

Chemical Hazards Produced by Certain Molds

- Aflatoxins
 - Peanuts, dried corn (maize), tree nuts, certain spices
 - Ochratoxin A
 - Coffee, raisins, wine, cereal grains, certain spices
 - Fumonisin
 - Deoxynivalenol (DON)
 - Wheat and barley
 - Zearalenone
 - Wheat and barley
 - Patulin
 - Fruits
- Factors that increase concern
 - Certain weather patterns, e.g., drought stress
 - Insect damage
 - Slow drying
 - Poor storage

Chemicals Used In Formulation

- Food additives
- Color additives
- Preservatives
- Nutritional additives
- Antimicrobials

Unintentionally or Incidentally Added Chemicals

- Cleaning chemicals
- Pesticides
- Industrial chemicals
- Heavy metals
- Drug residues
- Radiological hazards

Pesticides

- Must be registered with appropriate authority
 - EPA in U.S.
- Must be used according to label instructions
- Regulatory programs may address
 - Applicator licensure
 - Usage instructions
 - Official monitoring for residues
- Compliance
 - High compliance for U.S. operations
 - Imported product compliance rates vary

Industrial Chemicals

- Examples
 - Dioxins
 - Polychlorinated biphenyls
- Break down slowly in the environment and can be concentrated in the food chain

Heavy Metals

- Examples
 - Arsenic
 - Lead
 - Mercury
- May accumulate in plants or fish

Drug Residues

- Drugs are important for animal health but require management for safety and effectiveness
- Premarket approval is required and limited to specific uses
- Compliance with U.S. regulatory requirements is high but evaluation should consider potential occurrence in relevant products such as milk

Radiological Hazards

- A type of chemical hazard
- Potential sources:
 - Contaminated soil, water or air
 - Ingredients with radionuclides
 - Packaging materials
- Examples include strontium-96, iodine-131 and cesium-137

Chemical Hazards Potential Controls

- Supply-chain controls
 - Relevant to almost all chemical hazards
- Sanitation controls
 - Relevant to allergens
- Allergen controls
 - Relevant to allergens
- Process controls
 - Relevant to chemicals used in formulation

Chemical Hazards Summary

- Chemical hazards may include those that:
 - Occur naturally
 - Are used in formulation
 - Are unintentionally or incidentally present
- FDA approval considers specific use and long-term and short-term effects
- Supply-chain, sanitation, allergen and process preventive controls may be required to control hazards identified through hazard analysis

Physical Hazards

- Foreign objects
 - Glass and brittle plastic
 - Cuts, choking; may require surgery
 - Metal
 - Cuts, broken teeth; may require surgery
 - Wood and stones
- Choking hazards for young children

Choking Hazards for Young Children

- Small windpipe, underdeveloped swallowing and chewing increase choking risk
- Cylindrical and compressible foods present greatest risk
- No standards for foods but “small-parts test fixture” → used for toys

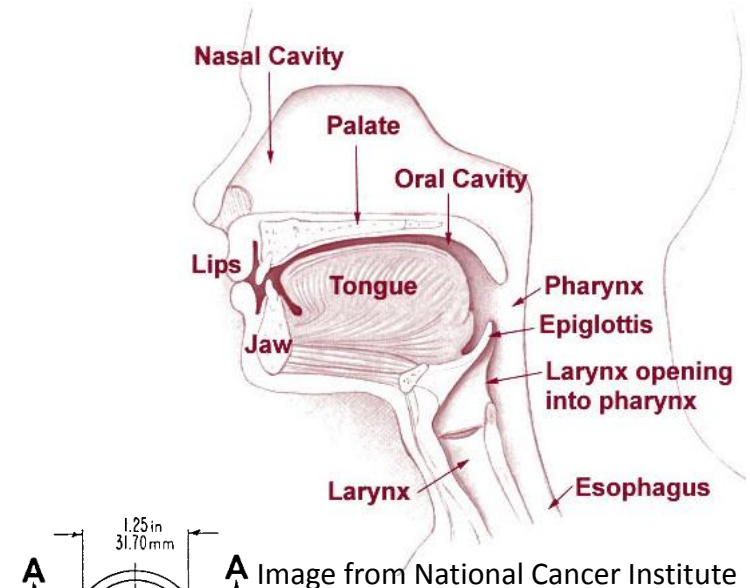
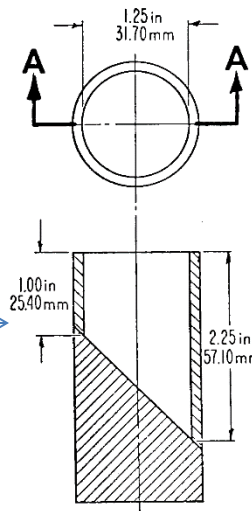


Image from National Cancer Institute



Section A-A

Image from Consumer Products Safety Commission

Economically Motivated Hazards

- Limited to hazards with a pattern of economically motivated adulteration in the past
- Include only those agents that can cause illness or injury
- When a preventive control is needed, a supply-chain program is typical

Chemical, Physical and Economically Motivated Hazards Summary

- Chemical (including radiological) and physical hazards may occur in foods
- Hazards, if not prevented and controlled, may seriously affect food safety
- Companies must know about hazards that may be in their products
- Preventive controls for hazards requiring them must be documented in the Food Safety Plan