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Session No.: SM3
**Product Safety – Risk Management
Fundamentals for the Safety
Professional**



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Chubb Group of Insurance Cos.
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Product Safety – Risk Management Fundamentals for the Safety Professional

Objectives

1. Gain an understanding as to the basics of product safety.
2. Identify the societal and business implications of product safety.
3. Introduce product safety risk management fundamentals.
4. Identify opportunities for the safety professional in product safety.



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Product Safety in the News - News Headlines

‘FAA Regulators Ground All Boeing 787 Dreamliners’

- January 16, 2013 Los Angeles Times

‘Safety Agency Widens Inquiry Into Repairs of Rental Cars’

- March 31, 2011 New York Times

‘U.S. Indicts Peanut Processors in 2009 Salmonella Outbreak’

- February 21, 2013 Chicago Tribune

**‘Laundry Detergent Pods an “Emerging Public Health Hazard”
Among Kids, Says CDC’**

- October 19, 2012 ABC News



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**Product Safety – Risk Management Fundamentals
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Benefits for the traditional Safety Professional

- **Product Safety in the Workplace**
 - Impact on employee safety
 - Procurement of products and machinery
 - Promoting off-the-job safety



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- **Job Enrichment**
 - Expanding range of safety influence
 - Broadening risk management & business skills
 - Contributing to product safety initiatives



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- **Career Opportunities**
 - Product safety role
 - Risk Manager



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**Product Safety – Risk Management Fundamentals
for the Safety Professional**

Common Skill Sets

Hazard Recognition	Knowledge of safety standards & regulatory requirements
Risk Assessment	Trend Analysis
Process Safety	Hazard Communication
Safety by Design	Incident Investigations
Ergonomics	Crisis Management
Behavioral Safety	
Safety Training & Instruction	



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Product Safety – Risk Management Fundamentals for the Safety Professional

Regulated Products

CPSC	Consumer Products
FDA	Food, Drugs & Medical Devices
USDA	Meats & related products
ATF	Alcohol Tobacco & Firearms
Coast Guard	Boats and Watercraft
EPA	Pesticides & related products
FAA	Aircraft
NHTSA	Cars, Cycles, Tires, Car Seats
NRC	Radioactive Materials



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FDA - Food Safety Statistics

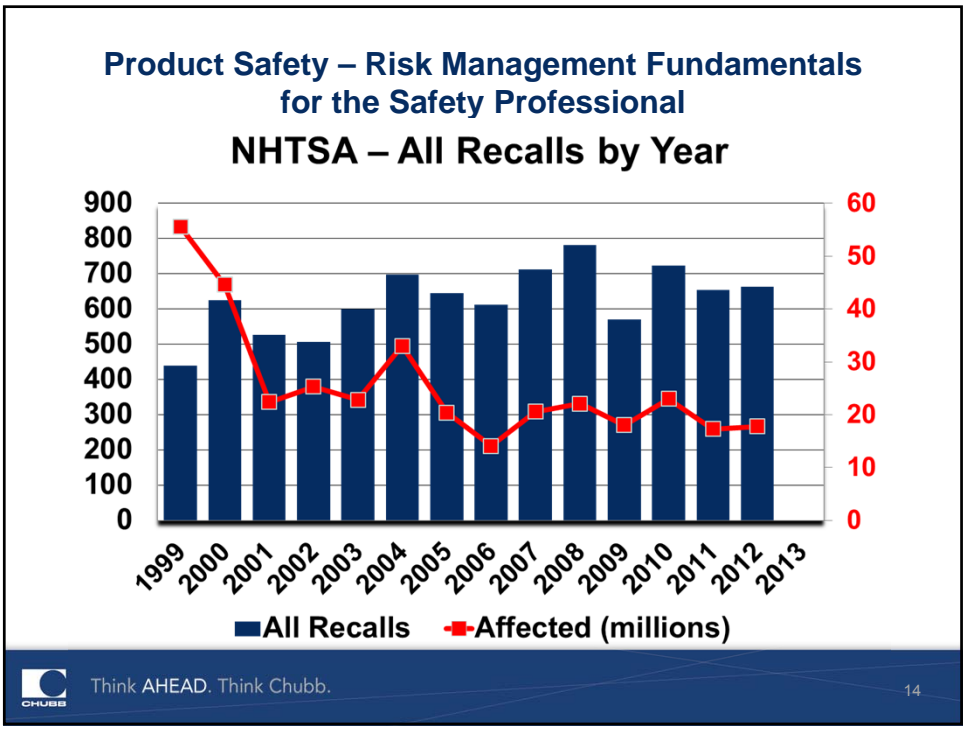
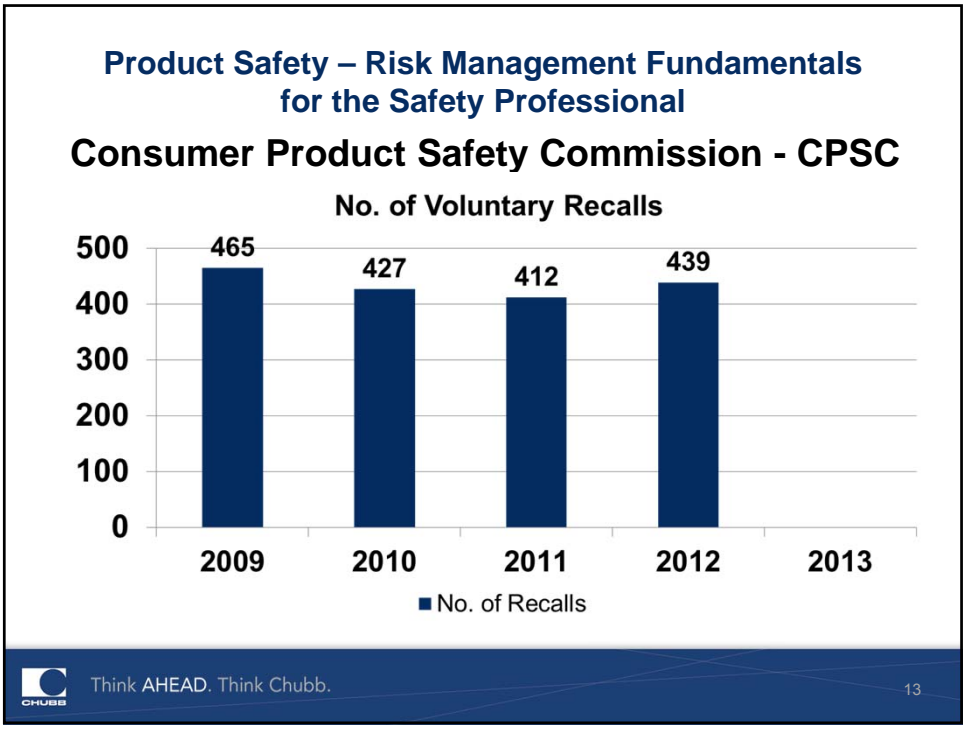
Each year in US Foodborne Illness causes:

- 48 Million Gastrointestinal Illnesses
- 128,000 Hospitalizations
- 3,000 Deaths



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Product Safety

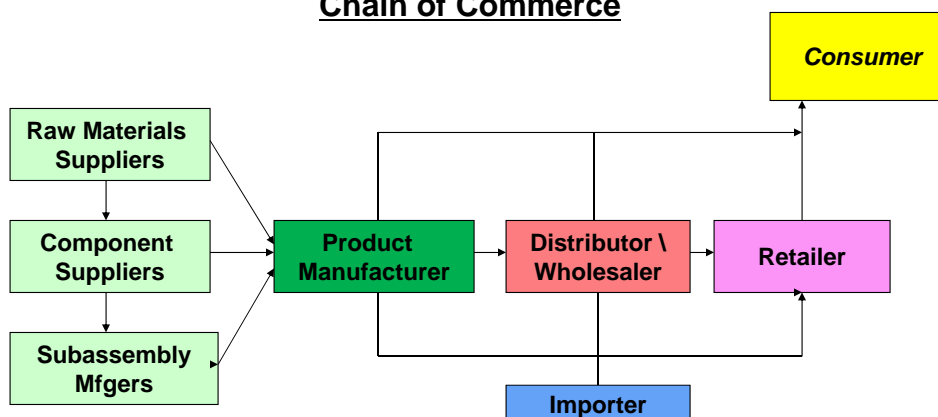
- **Expectations**
 - Societal
 - Consumer
 - Regulatory
 - Legal
- **Voluntary Standards**
 - US
 - International
- **Regulations**
 - US
 - International



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Chain of Commerce



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Counterfeit Products

Top Ten Product Categories –

- | | |
|-------------------------------|---------------------------|
| 1. Footwear | 6. Computers/Hardware |
| 2. Consumer Electronics | 7. Media |
| 3. Handbags/Wallets/Backpacks | 8. Pharmaceuticals |
| 4. Wearing Apparel | 9. Jewelry |
| 5. Watches/Parts | 10. Toys/Electronic Games |

Safety & Security Product Categories Include:

- | | |
|----------------------------------|-----------------------|
| * Pharmaceuticals | * Electrical Articles |
| * Critical Technology Components | * Batteries |
| * Sunglasses | * Personal Care |

Source: U.S. Customs and Border Protection, Intellectual Property Rights, Seizure Statistics:
Fiscal Year 2009



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The Product Life Cycle

- I. Concept
- II. Design
- III. Manufacturing / QA
- IV. Marketing
- V. Installation / Service / Repair (if applicable)
- VI. Post-Marketing Product Surveillance
- VII. Disposal



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Product Concept Considerations:

- Use or Application
- Need
- Market
- End Users
- Intended Use
- Alternate Uses / Abuse / Misuse
- Anticipated Hazards
- Achieving Product Safety



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**Product Safety – Risk Management Fundamentals
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Hierarchy of Controls:

- Eliminate the Hazard
- Guard the Hazard
- Instruction / Training
- Warning Labels – Communicate Hazard



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Hazard Identification – Potential Hazards

Hazard - Property Damage

- Fire / Explosion
- Smoke Damage
- Water Damage / Mold
- Contamination
- Building Damage
- Equipment Damage

Hazard - Bodily Injury

- Flammable / Burn
- Toxic / Poison
- Choking
- Strangulation
- Electrical Shock
- Laceration / Abrasion



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Product Design Considerations:

- Application of Product Concept Criteria
- Regulatory Requirements
- Voluntary Standards
- Critical Characteristics / Safety Factors
- Product Safety Risk Assessment
- Design Reviews
- Prototype Evaluation & Testing
- Life Cycle Assessment
- Product Safety Information



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Manufacturing and QA Considerations:

- **Manufacturing Requirements / Validation**
- **In-house versus Subcontracted**
- **Supplier & Subcontractor Qualification**
- **Inspection & Testing Criteria / Verification**
- **Product Safety Implications**
- **Nonconformance Management**
- **Product Identification & Traceability**



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Marketing:

- **Sales Network (in-house vs. outside)**
- **Marketing Materials**
- **Use of Sales ‘Puffery’**
- **Product Feedback & Analysis (inc. Social Media)**
- **Product Traceability**
- **Recall Policies & Procedures**



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Installation, Service and/or Repair:

- In-house vs. Outside Resources
- Standardized Procedures
- Technical Communications
- Documentation and Review
- Post-Marketing Safety Actions
 - Retrofits
 - Programming



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Product Service Life & Disposal:

- Product Technical Support
- Continuing Product Feedback
- Failure Analysis
- Documentation Retention
- Post-Marketing Safety Actions
- Specialized Disposal Requirements



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Product Safety – Risk Assessment

Risk = Hazard Severity X Hazard Probability

Product

Scenario: _____

Hazard	Statement of Exposure	Current State				Post-Mitigation				
		Description of Controls	Control	Severity	Probability	Description of Controls	Control	Severity	Probability	Overall Risk

Existing Controls

Safety Enhancements

Ratings –
- Controls
- Probability
- Severity
Overall RISK

Modified Ratings –
- Controls
- Probability
- Severity
Overall RISK

Control

a. Elimination
b. Substitution
c. Engineering Controls
d. Administrative Controls
e. Personal Protective Equipment
f. No Controls

Severity Risk Rating

1. Negligible
2. Marginal
3. Substantial
4. Critical
5. Catastrophic

Probability

1. Improbable
2. Remote
3. Occasional
4. Probable
5. Frequent

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Product Safety – Risk Assessment

Severity of Occurrence	Catastrophic Death or permanent total disability (5)	Medium Management review needed	Serious Risk reduction recommended	High Risk reduction necessary	High Risk reduction necessary	High Risk reduction necessary
	Critical Disability in excess of 3 months (4)	Medium Management review needed	Serious Risk reduction recommended	Serious Risk reduction recommended	High Risk reduction necessary	High Risk reduction necessary
Substantial Lost workday case (3)	Low Acceptable risk	Medium Management review needed	Serious Risk reduction recommended	Serious Risk reduction recommended	High Risk reduction necessary	High Risk reduction necessary
Marginal Medical injury (2)	Low Acceptable risk	Medium Management review needed	Medium Management review needed	Serious Risk reduction recommended	Serious Risk reduction recommended	Serious Risk reduction recommended
Negligible First aid or minor medical treatment (1)	Low Acceptable risk	Low Acceptable risk	Low Acceptable risk	Medium Management review needed	Medium Management review needed	Medium Management review needed
Risk Rating	Improbable Very unlikely – may assume exposure will not happen (1)	Remote Not likely to occur (2)	Occasional Likely to occur sometime (3)	Probable Likely to occur several times (4)	Probable Likely to occur several times (4)	Frequent Likely to occur repeatedly (5)
Probability of Occurrence						

Severity score examples provided for bodily injury.

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Product Safety Information

Product Warning Label Signal Words - ANSI Z535.4

NOTICE - This signal word should not be associated directly with hazard or hazardous situations and not used in place of danger, warning, or caution.

DANGER - indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.

WARNING - indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.

CAUTION - indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Source: ANSI Z535.4:2007 Product Safety Signs and Labels
ANSI Z535.6:2006 Product Safety Information in Product Manuals, Instructions and Other Collateral Materials



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Product Warning Labels



Note: Used with permission of Clarion Safety Systems, LLC



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Product Safety Information

Product Instruction Manuals – ANSI Z535.6



WARNING:

To reduce the risk of fire, electric shock, or injury:

- Do not immerse.
- Always connect to a properly grounded outlet.
- Do not leave machine unattended.
- Use indoors only.
- Do not expose hair, loose clothing, fingers or body parts to openings or moving parts.
- Do not allow to be used as a toy.
- Close attention is necessary when used by or near children.



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What is Product Liability?

Product Liability - “refers to the legal liability of manufacturers and sellers to compensate buyers, users, and even bystanders for damages or injuries suffered because of defects in goods purchased.”

Source: Black’s Law Dictionary, 1089 (5th Edition, 1979)



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Legal Theories of Recovery

- **Negligence**
- **Strict Liability**
- **Breach of Warranty**
 - **Implied**
 - **Expressed**



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Negligence

“Negligence is the failure to do something which a **reasonably careful person** would do, or the doing of something which a reasonably careful person would not do”

Three Categories

Negligent Design
Negligent Manufacturing
Negligent Failure to Warn

Sources: Mangrum v. Pigue, 2004 Ark. Lexis 686 & Mark A. Kinzie & Christine F. Hart, (2002). *Product Liability Litigation*. Delmar “West Legal Studies series “.



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Breach of Warranty

Express Warranty –

“A statement by a manufacturer or seller, either in writing or orally, that his **product is suitable for a specific use and will perform in a specific way.**”

Implied Warranty of Merchantability -

“An automatic warranty, implied by law, that a manufacturer’s or dealer’s **product is suitable for either ordinary or specific purposes and is reasonably safe for use.**”

Source: James F. Thorpe & William H. Middendorf. (1979). *What Every Engineer Should Know About Product Liability*. New York, NY: Marcel Dekker, Inc.



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Strict Liability in Tort

This is the “legal theory that a manufacturer of a product is liable for injuries due to product defects, without the necessity of showing negligence of the manufacturer.”

Key Factors

- The conduct of the manufacturer is irrelevant.
- Negligence on the part of the manufacturer need not be proven.
- Plaintiff must prove the product was defective, unreasonably dangerous and the proximate cause of bodily injury or property damage.

Source: James F. Thorpe & William H. Middendorf. (1979). *What Every Engineer Should Know About Product Liability*. New York, NY: Marcel Dekker, Inc.



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Strict Liability – Defect Criteria Varies

Restatement of Torts (Second): Product Liability

Defect - “Unreasonably dangerous to the user”

Restatement of Torts (Third); Product Liability

Defect – “Foreseeable risk of harm could have been reduced or avoided by the adoption of a reasonable alternative design, and the omission of the alternative design renders the product not reasonably safe.”



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Three types of Product Defects:

- Design Defects
 - Inherent design defects
 - Exist before the product is manufactured
 - Unreasonably dangerous due to design flaw



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- Defects in Marketing
 - Improper instruction and/or a failure to warn consumers of potential hazards or dangers



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Potential Product Liability Defenses

- Not your product
- Open & Obvious
- Not a Foreseeable Misuse
- Substantially Altered
- Assumption of Known Risk
- Preemption

Source: Terrence F. Kiely & Bruce L. Ottley (2006). *Understanding Product Liability Law*. Newark, NJ: Matthew Bender & Company, Inc., a member of the LexisNexis Group.



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Products

- **Discontinued**
- **Prior**
- **Current**
- **Acquired**
- **Future**



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Product Failure Modes

- **Normal Operating Modes**
- **Failure Modes**
- **Maintenance Modes**
- **Reasonably Anticipated Misuse**



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Product Safety & Liability Risk Management

Management Policies and Procedures

- Management commitment to product safety
- Established Quality Management Systems and Processes
- Structured product safety auditing procedures
- Risk minimization initiatives
- Risk transfer efforts



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In Summary –

- Product safety is an important business priority for manufacturers, distributors and importers.
- Safety professionals can make significant contributions to enhance product safety.
- Consider expanding your involvement in this important safety area.



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Questions?



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Session Surveys

Please complete the evaluation survey.



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