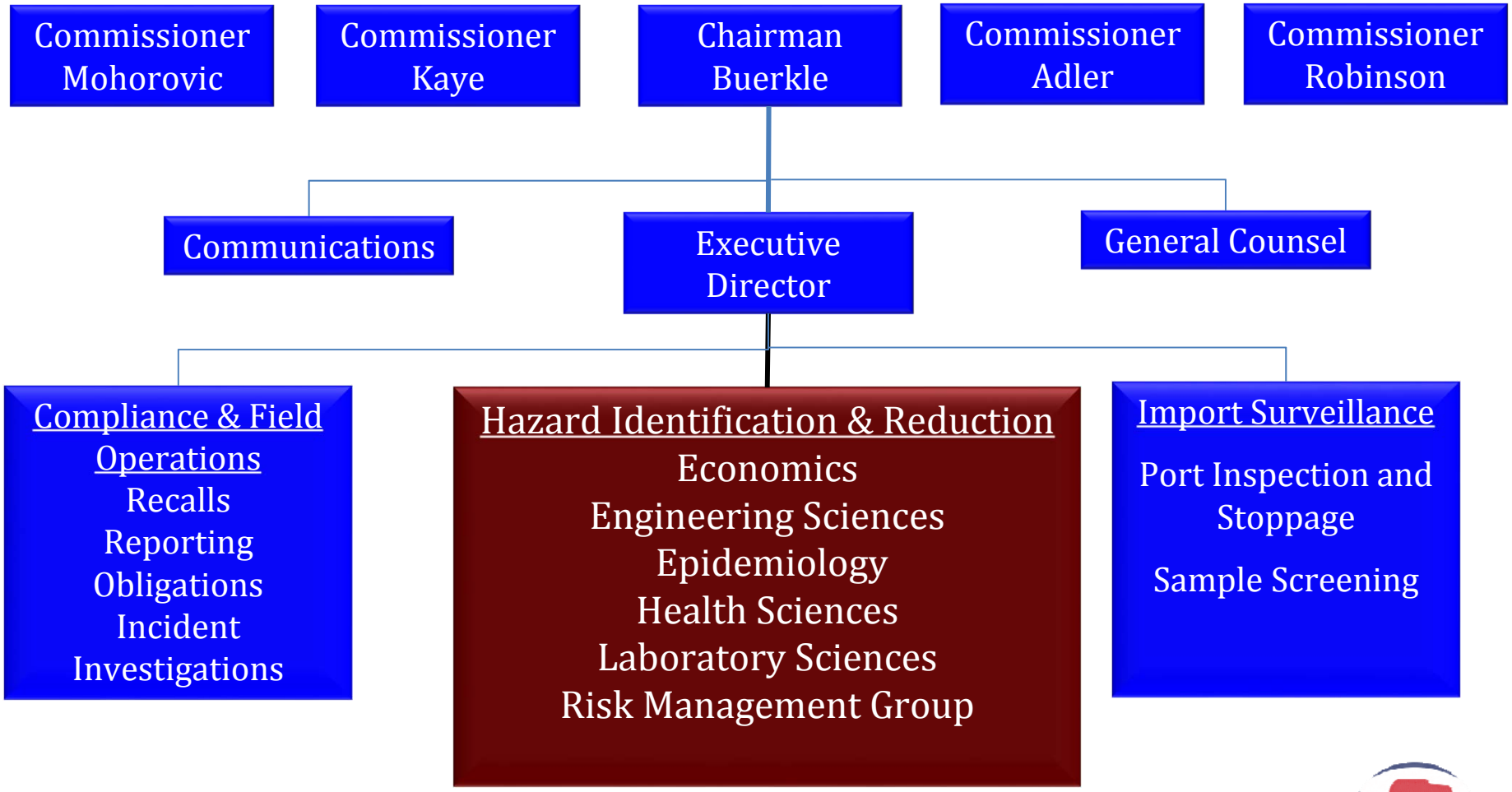
UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

Risk-Informed Decision Making

*This information was prepared by the CPSC staff; it has not been reviewed or approved by, and does not necessarily represent the views of, the Commission.

CPSC Organization



This is a simplified functional organization chart that does not include many key support groups within the CPSC, including Facilities Services, Human Resources, Information Technology, Budget, Planning, Inspector General, Equal Employment, Office of the Secretary, Small Business Ombudsman, and Legislative Affairs.

Risk Informed Decision Making (RIDM)

RIDM is:

- Bringing together the best available information in a formal or informal risk assessment to inform decision makers in their recommendations for agency actions.

- RIDM recognizes information will often be incomplete or unavailable.
  - In such cases, the staff provides its best judgment about this uncertainty, based on its expert knowledge, in lieu of developing this information.

"How much" to manage risk?

- *Prevent or reduce unreasonable risk*
  - Consumer Product Safety Act (CPSA)
- *Costs must bear a reasonable relationship to benefits*
  - CPSA
- *Consider cost and benefits*
  - Executive Order 12866

CPSC Risk Management Principles

Guided by:

- Consumer Product Safety Act (CPSA) – 16 CFR 1009.8, “Policy on Establishing Priorities for Commission Action”

- CPSC Directive 0606.1, “Risk-Based Analysis: Information to Be Considered During Decision Making,” dated September 3, 2003.

CPSA 16 CFR 1009.8 CRITERIA

Eight (8) general criteria to be applied for establishing priorities:

- Frequency and severity of injuries
- Causality of injuries
- Chronic illness and future injuries
- Cost and benefit of CPSC action
- Unforeseen nature of the risk (“hidden” hazard?)
- Vulnerability of the population at risk
- Probability of exposure to the hazard
- Additional criteria

Key Factors and Questions
Step 1 – Risk Identification

Factors considered in the identification of product hazards:

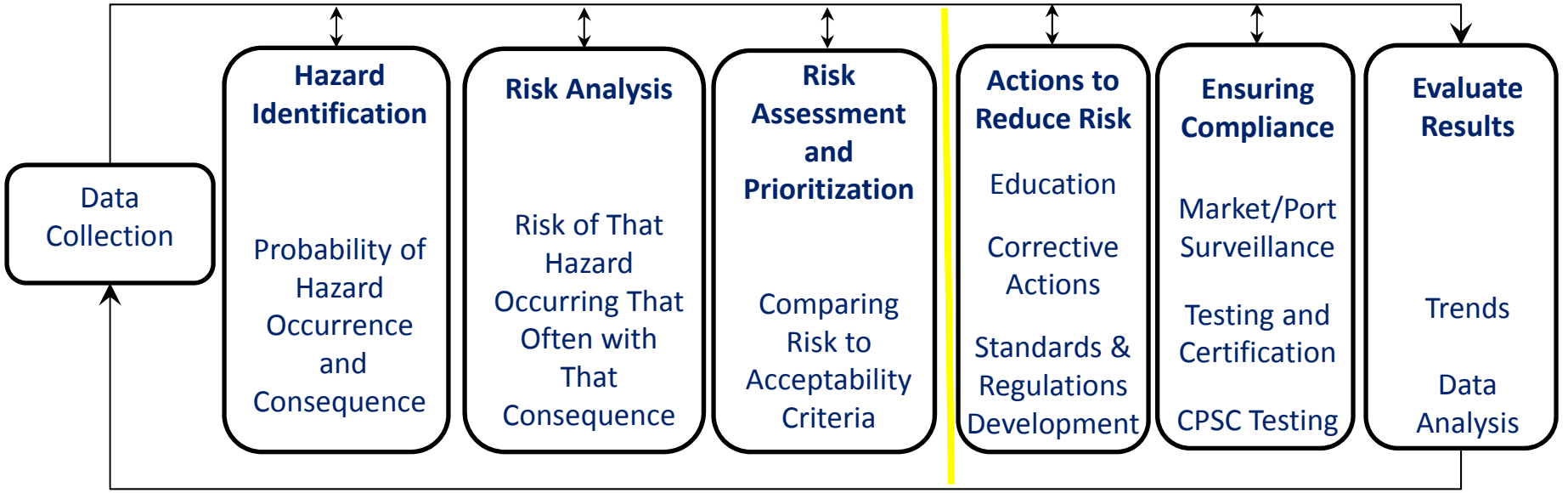
1. **Frequency and severity of injuries**
   How many injuries and deaths are associated with the product or hazard? What are the trends? What are the hazard patterns? Are there comparable hazards with similar products?
2. **Exposure/Availability**
   How many products in use? What is the frequency of exposure to the risk of injury? What is the likelihood that such exposure will result in injury?
3. **Causality of injuries**
   What is relationship between consumer, environment, and product?
4. **Foreseeability of the risk**
   How likely is the sequence of events (interaction of the consumer, the product and the environment) that creates the risk of injury?
5. **Vulnerability of the population at risk.**
   To what degree is product associated with injuries to such populations as children, individuals with disabilities, and older adults (65 +)? To what degree are they able to appreciate the risk and take measures to protect themselves?

Key Questions
Step 2 – Risk Reduction

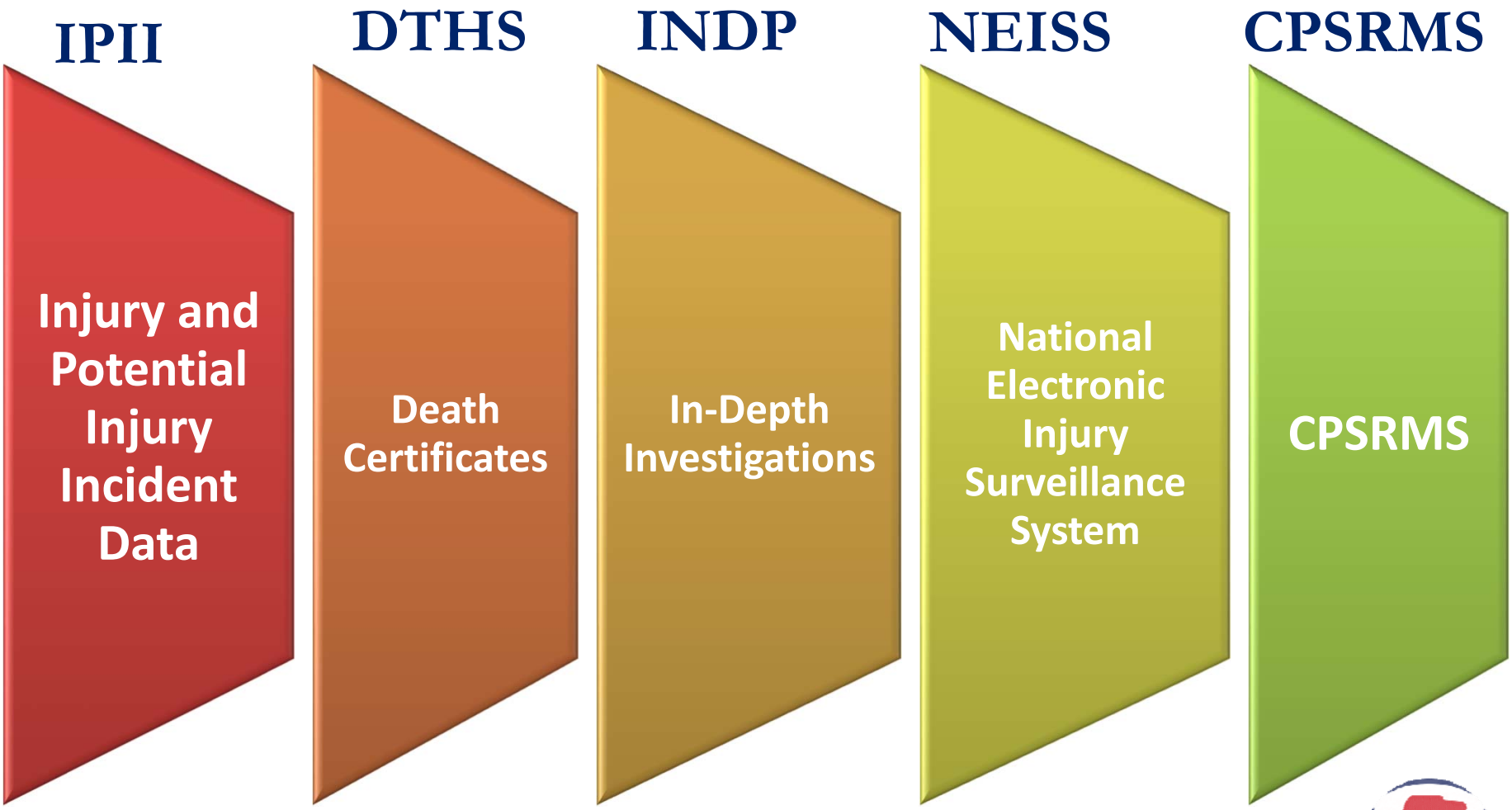
Four categories of questions should to be considered to determine remedies, if any, appropriate to address potential risks of injury.

1. **History -** What past Commission activities and staff initiatives are relevant to the hazard? What were the results of the activities and initiatives?
2. **Addressability -** Is the hazard amenable to Commission action? What options are feasible? What are the pros and cons of each option?
3. **Effectiveness -** Are remedies or activities under consideration commensurate with the risk of injury? What is the potential for the remedies or activities to reduce the risk of injury?
4. **Costs and Benefits -** What are the potential costs (including costs to the agency) and benefits of CPSC action? What stakeholder considerations are there?
   - Sometimes cost benefits are not applied, e.g. congressional mandate

CPSC Risk Management Process



Data Collection Systems



Injury and Potential Injury Incident Database (IPII)

- Anecdotal reporting to CPSC
- Product detail (*e.g.*, make and model) and scenarios detail is often available

DEATH CERTIFICATES DATABASE (DTHS)

- Contracts with 50 states
- Purchase approximately 8,000 per year
- Time lag
- Daily review
- Analytical use

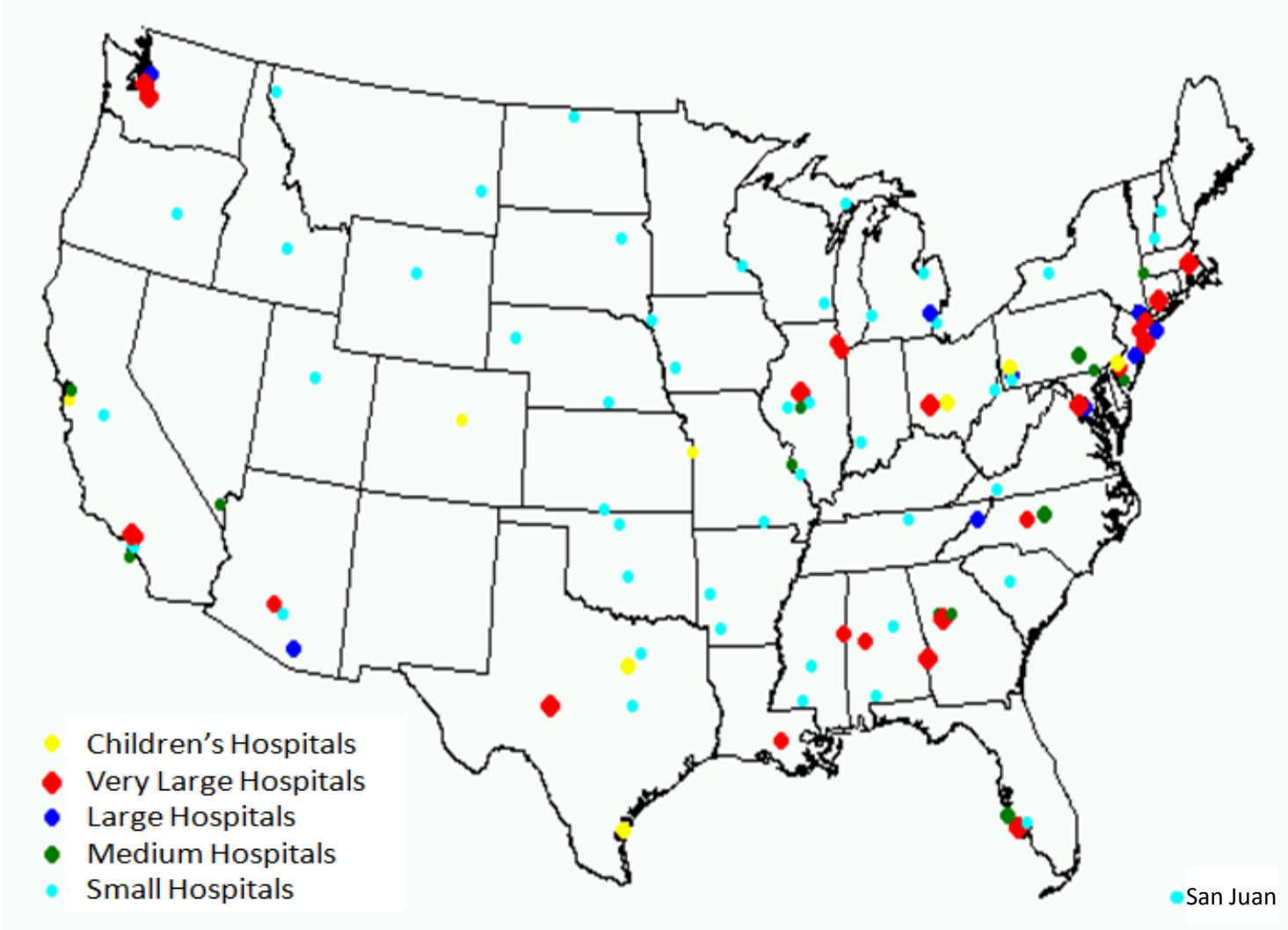
In-Depth Investigations Database (INDP)

- Field Investigations
  - Follow-up investigations of source documents, which are reports of incidents, deaths, or hospital injuries
  - On site or telephone
  - Local-level collaboration
    - ✓ Medical examiner
    - ✓ Police
    - ✓ Fire
  - Sample collection opportunity

National Electronic Injury Surveillance System (NEISS)

- National sample
  - Data collected from approximately 100 hospital emergency departments around the country
  - Data weighted to provide consumer injury estimates nationwide
- Multilevel system
  - About 395,000 consumer product-related injury reports annually, of which 300,000 are collected for use by other federal agencies
- Data submitted daily by hospital coders to CPSC

Map of NEISS Hospital Locations



Other Data Sources

- Additional Surveillance Data from:
  - National Burn Center Reporting System
  - National Fire Incident Reporting System
  - National Center for Health Statistics Mortality Data
- Collection of actual samples or a similar sample involved in an incident, purchased at a retailer or seized at a port

CONSUMER PRODUCT SAFETY RISK MANAGEMENT SYSTEM

- In place since 2011
  - Contains all information in IPII, DTHS, INDP (and some NEISS)
  - SaferProducts.gov
    - Public facing, searchable component, SaferProducts.gov, contains all reports cleared for public release

HAZARD IDENTIFICATION

Daily

- Triage of Incoming Incidents
- Referral to Subject Matter Expert Teams (IPTs)

Weekly

- Expert Review
- Assign Keywords for Pattern Identification
- Recommend Sampling

Pattern Assessment

- Frequency of Reporting – Product, Hazard, Severity, Age
- Product Safety Assessments

Detailed Analyses

- Trend Analyses
- Risk Definition and Collaborative Mitigation Strategies

Hazard Identification

Interdisciplinary teams of experts review incidents and/or physical samples to:

- Identify hazards described
- Examine chain of events
- Review circumstances of incident, modes of failure
- Identify incident hazard patterns
- Screen for trends and emerging hazards
- Determine compliance with standards

Risk Analysis

Based on the evaluation of data and/or physical samples, interdisciplinary teams of experts:

- Make qualitative evaluations of risk, based on how often the hazards may occur and severity of incidents
- Capture all risk analyses in internal database for longer-term pattern analyses

Risk Assessment

- Based on the results of the risk analysis, the CPSC staff compares the evaluated risk to the acceptable level of risk.

- The criteria for acceptable level of risk is based on:
  - Nature of hazard (level of human involvement, etc.)
  - Likelihood of occurrence
  - Severity of injury
  - Vulnerable populations

PRIORITIZATION

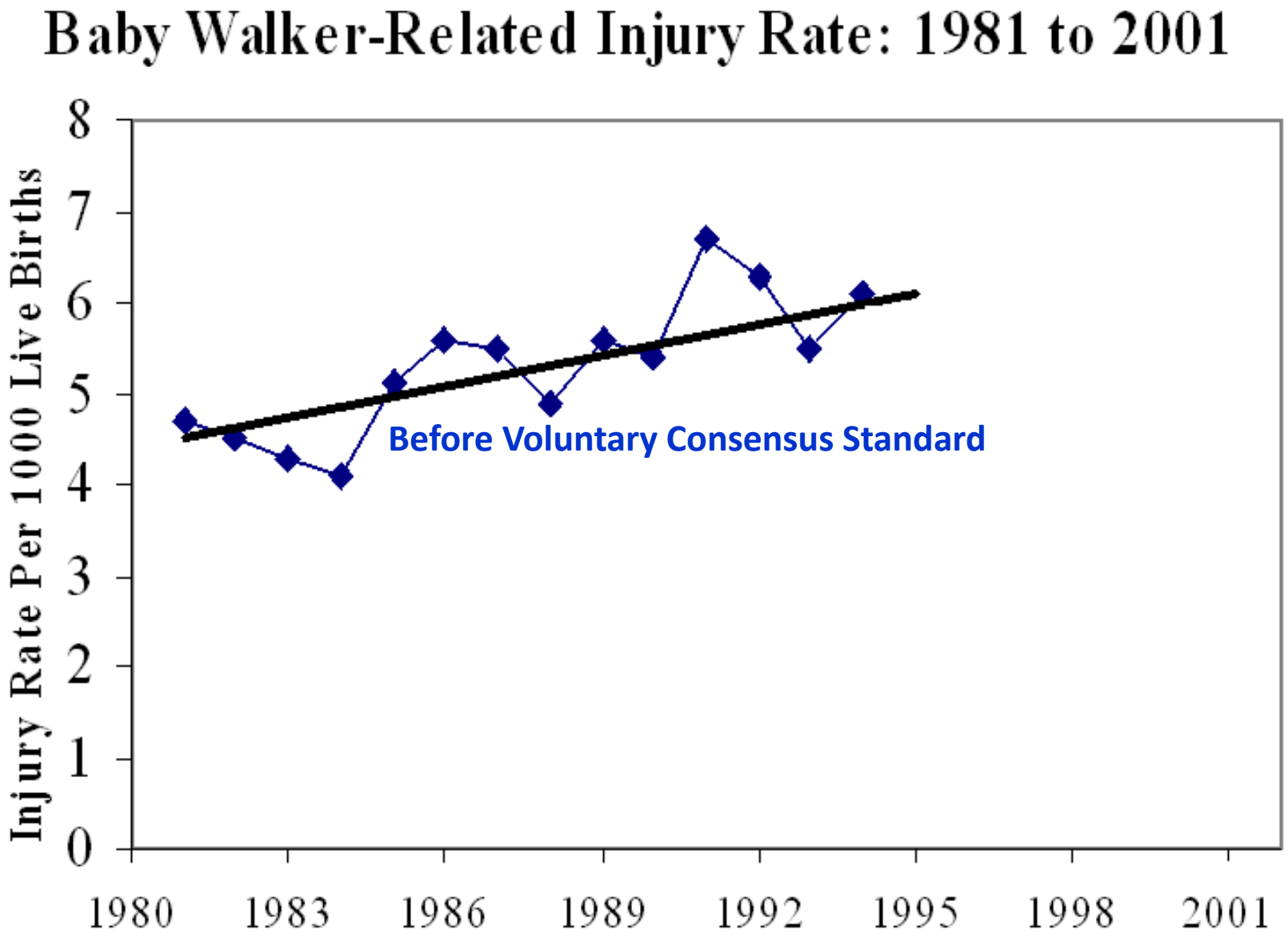
- Based on “the gap” between the current risk posed by the product and acceptability criteria
- Influenced by the degree to which CPSC actions are estimated to mitigate the risk (addressability)

Actions to Reduce Risk

- Strategy: Reduce/maintain risk at acceptable levels

- Actions to reduce risk to acceptable levels:
  - Change or create voluntary consensus standards
  - Change or create regulations
  - Reach out to manufacturers, distributors, and importers
  - Educate the public

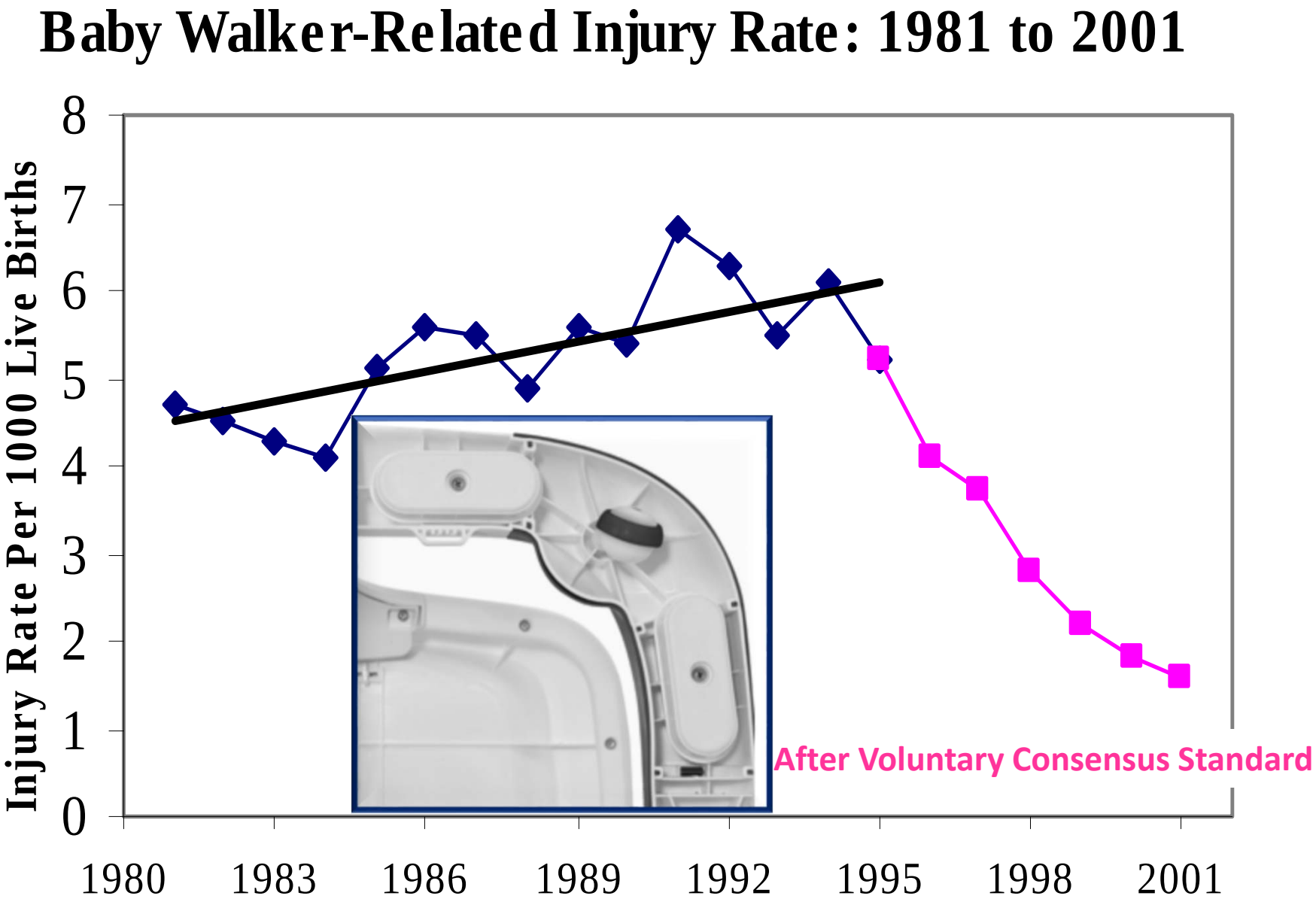
HAZARD IDENTIFICATION – BABY WALKER



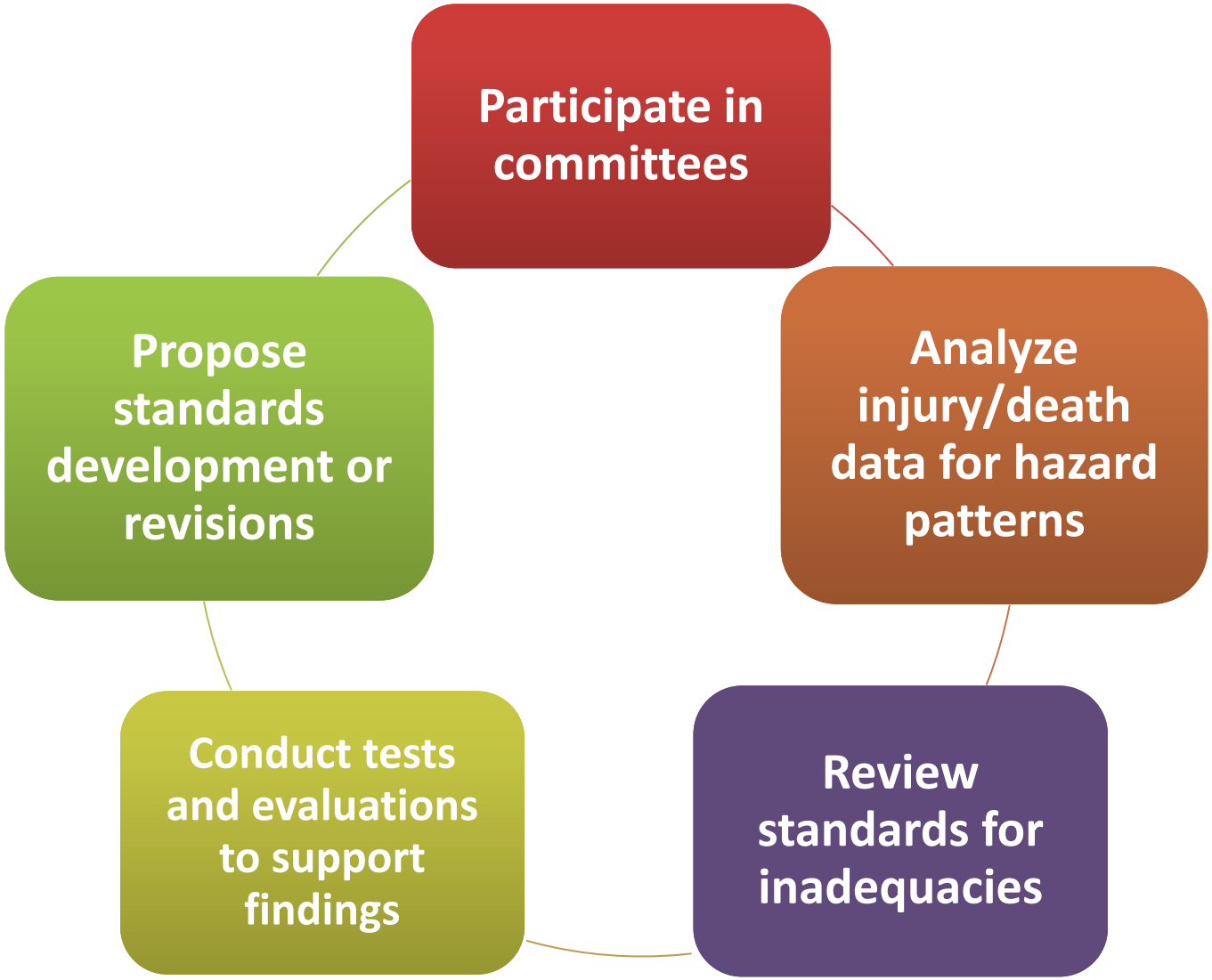
Risk Analysis – Baby Walker

84% of severe injuries resulted from falling down stairs

Action Taken to Reduce Risk – Friction Pads



CPSC Voluntary Consensus Standards Monitoring



Single Load Liquid Laundry Packets

The Hazard

- **Children:** Ingestion, ocular, and dermal exposures from children gaining access to packets either directly from packaging or left loose on the floor.
- **Adults:** Ocular and dermal exposures, from tearing apart stuck-together packets, or not fully dissolved packets on clothing coming in contact with skin. Elderly adults are ingesting packet contents.

Addressing the Hazard

- CPSC worked with manufacturers & other stakeholders thru ASTM International to develop a voluntary consensus standard.
- Sept. 2015 -- Publication of ASTM F3159-15 *Consumer Safety Specification for Liquid Laundry Packets*
- Addresses labeling and packaging individually wrapped liquid-detergent.

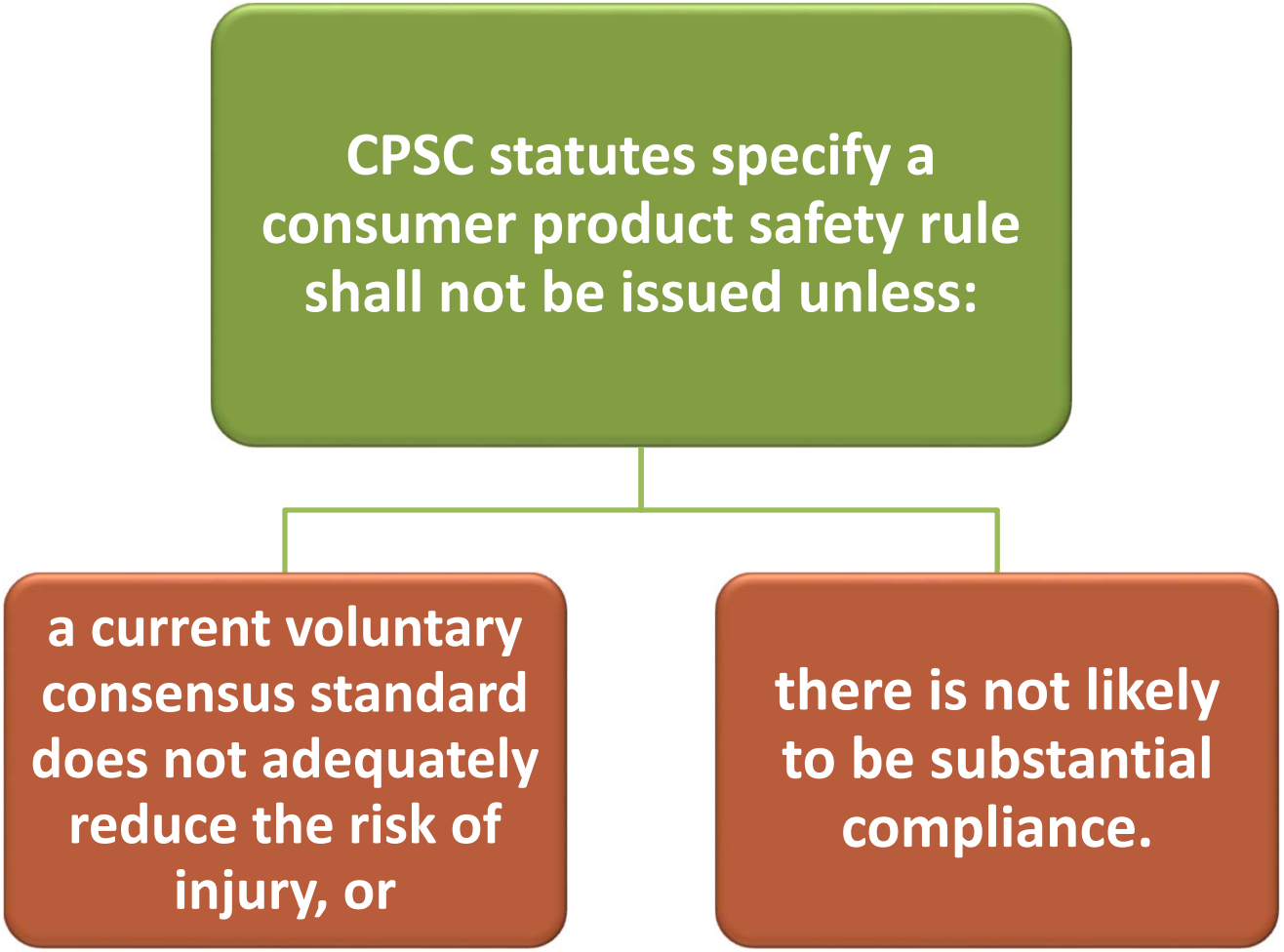
Firepots and Gel Fuels

- Identified as an emerging hazard in June 2011, after a severe injury was reported.
- Small portable, decorative, lighting product for indoor or outdoor use.
  - Heat-resistant base with a metal burn cup
  - Uses an alcohol-based gel fuel
  - Clean-burning flame
  - Not a candle or torch

  - https://www.youtube.com/watch?v=U0WMrfw6utg

REGULATIONS

Regulatory process can be started by vote of the Commission or by a petition from an interested party



Ensuring Compliance With Risk Management Strategy

Responsibility is shared among manufacturers, importers, retailers and CPSC.

- Follow CPSC regulations, voluntary consensus standards, and best manufacturing practices
- Testing and certification
- Market surveillance
- CPSC testing
- Reporting Requirements – Section 15

Market Surveillance Activities

Retail

- Program plan for regulated products; surveillance for defects and other risks

Internet

- Check for conformity with regulations and for recalled products

Ports and Airports

- Investigators at key ports of entry
- Analysts identify most likely at-risk products

Voluntary Consensus Standards and Recalls

In some cases, failure to comply with a voluntary consensus standard indicates to the CPSC that a product is defective and presents a substantial hazard.

Example: These lights do not meet the provisions of the Underwriters Laboratory (UL) standard that CPSC has specified in a rule. They can overheat and pose a fire and shock risk.

CPSC can seek a recall.

VIOLATIONS/PROHIBITED ACTS

- Manufacturing, distributing, or importing any product that does not comply with a mandatory standard
- Failing to report information as required by CPSC statutes
- Selling a recalled product
- Exporting a recalled product for sale

Ensuring Compliance With Risk Management Strategy

Compliance actions may include:

- Stop sale
- Design change
- Recall from consumer and/or at distribution level
- Repair, replacement, and/or refund
- Civil penalties $110,000 per violation, and from $1,250,000 to over $16,025,000 for aggregate violations
- Criminal penalties possible for *willful* violations

Evaluate Results

CPSC performs data-driven evaluations to evaluate the effectiveness of actions:

- Likelihood of occurrence
- Severity of injuries
- Compliance

CPSC's Risk Management Group (RMG)

- In 2016 RMG established
  - Division dedicated to Risk Management
  - Focus on commitment to risk-informed decision making
- Structure
  - Led by a Director,
  - Five Program Area Risk Managers (PARMs)
    - Lead six program areas: children's, Chemical Nano and Emerging Materials (CNEM), Combustion, Electrical, Fire, Mechanical Recreational Sports and Seniors (MRSS)
  - Voluntary Standards Coordinator (VSC)
  - Product Safety Assessment (PSA) Coordinator
- Main duties
  - identifying, analyzing and managing product safety risks
  - evaluating the impact of risk treatments implementation

Identifying Emerging Trends and Technologies

- Smart Technology, or the “internet of things”
- Wearables/Implantables/Smart textiles
- Personal transportation products
- An aging population; “aging in place”; multi-generational homes
- “Big Data” or large data set analytics
- Virtual reality/augmented reality devices
- 3D Printing; in-home manufacturing
- Potential Hazards Associated with Emerging and Future Technologies

Risk Discussion: What could go wrong?

- Smart Technology (The Internet of Things)
  - Smart-enabled gas grills
  - Smart toaster ovens
- Ride-on suitcases
- Autonomous off road vehicles
- High energy density home power systems