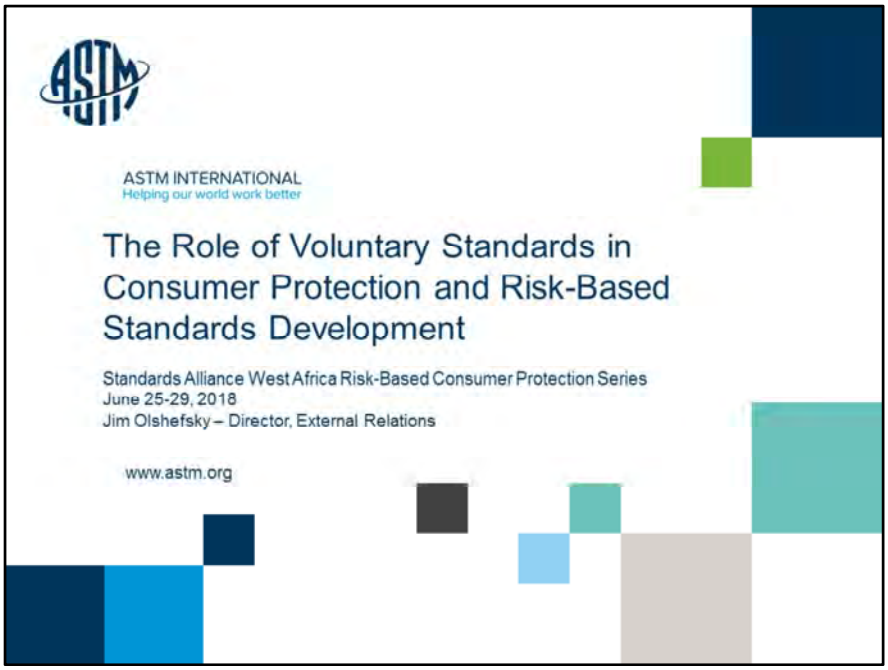

ASTM INTERNATIONAL
Helping our world work better
The Role of Voluntary Standards in Consumer Protection and Risk-Based Standards Development
Standards Alliance West Africa Risk-Based Consumer Protection Series
June 25-29, 2018
Jim Olshefsky – Director, External Relations
www.astm.org

Touching Every Part of Everyday Life

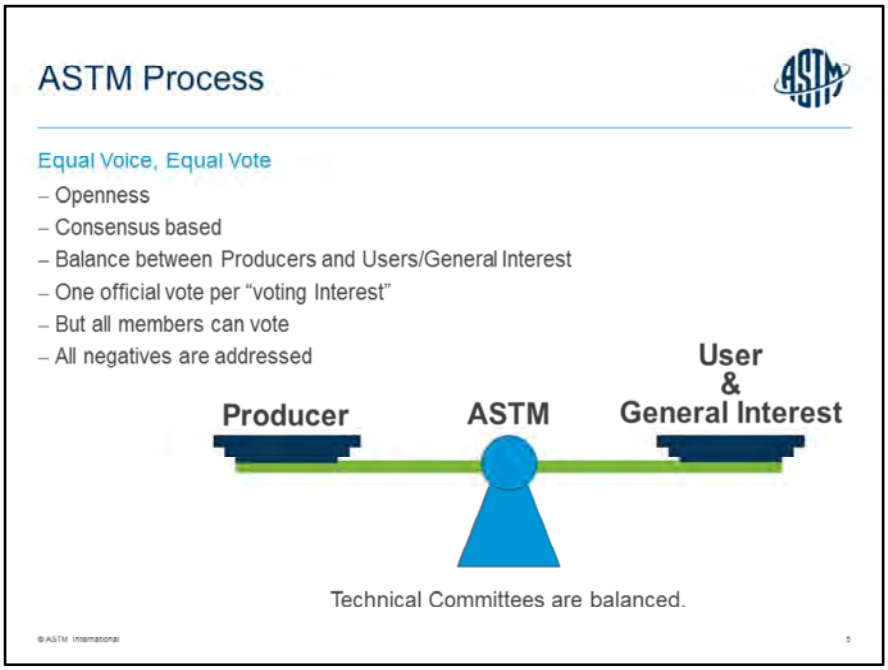
Introduction

- 12,700+ ASTM standards operate globally across borders, disciplines, and industries
- Harnessing the expertise of over 34,000 members worldwide
  - Relying on our members' expertise and commitment – their good science, good engineering and good judgment
  - Recognizing expertise not geography – members from 150 nations
- Standards for manufacturing and materials, products and processes, systems and services
- Standards are used voluntarily and cited in Regulation or contract
- Our standards help: consumers, businesses, manufacturers, innovators and governments

– ASTM is one of the world's largest SDOs, but it's the scale of our involvement and influence that counts for more.
– Complies with the six WTO principles for international standards development: transparency, openness, consensus, relevance, coherence, development dimension
– We work across political, cultural and geographic borders – recognizing expertise, not country of origin. This promotes a massive range of activity and a phenomenal exchange of knowledge.
– Trusted and known for market relevance and technical quality, our standards are the choice for many global industries – 49% outside the USA.
– We also believe in the power of standards to inspire and enable people and economies.
– Our global outreach activities increase understanding about standards and their application.
– And our Memorandum of Understanding Program provides tangible encouragement to developing economies.

ASTM Memorandums of Understanding

ASIA	EUROPE	CENTRAL & SOUTH AMERICA	CARIBBEAN	MIDDLE EAST & NORTH AFRICA	EASTERN, WESTERN & CENTRAL AFRICA	SOUTHERN AFRICA
BANGLADESH	ALBANIA	BOLIVIA	ANTIGUA AND BARBUDA	AFGHANISTAN	ARSO	ANGOLA
BHUTAN	ARMENIA	CHILE	BAHAMAS	BAHRAIN	BURUNDI	BOTSWANA
BRUNEI DARUSSALAM	AZERBAIJAN	COLOMBIA	BARBADOS	EGYPT	CAMEROON	MALAWI
CAMBODIA	BOSNIA	COSTA RICA	BCLIZE	GSO	COTE d'IVOIRE	MAURITIUS
CHINA	BULGARIA	ECUADOR	CROSQ	IRAQ	DEM REP CONGO	NAMIBIA
INDONESIA	CROATIA	EL SALVADOR	DOMINICA	ISRAEL	ETHIOPIA	SEYCHELLES
KOREA	EASC	GUATEMALA	DOMINICAN REPUBLIC	JORDAN	GAMBIA	SADC
LAO	GEORGIA	HONDURAS	GRENADA	KUWAIT	GHANA	SOUTH AFRICA
MALAYSIA	KAZAKHSTAN	NICARAGUA	GUYANA	MOROCCO	KENYA	SWAZILAND
MONGOLIA	KOSOVO	PANAMA	HAITI	OMAN	MOZAMBIQUE	ZAMBIA
MYANMAR	MOLDOVA	PARAGUAY	JAMAICA	PALESTINE	NIGERIA	ZIMBABWE
NEPAL	MONTENEGRO	PERU	MONTSERRAT	QATAR	RWANDA	
PAKISTAN	ROMANIA*	URUGUAY	ST. KITTS-NEVIS	SAUDI ARABIA	SIERRA LEONE	
PAPUA NEW GUINEA	RUSSIA		ST. LUCIA	TUNISIA	SENEGAL	
PHILIPPINES	SERBIA		ST. VINCENT - GRENADINES	TURKEY	TANZANIA	
SINGAPORE	UKRAINE		SURINAME	U.A.E.	UGANDA	
SRI LANKA			TRINIDAD & TOBAGO	YEMEN		
TAIWAN						
THAILAND						
VIETNAM						

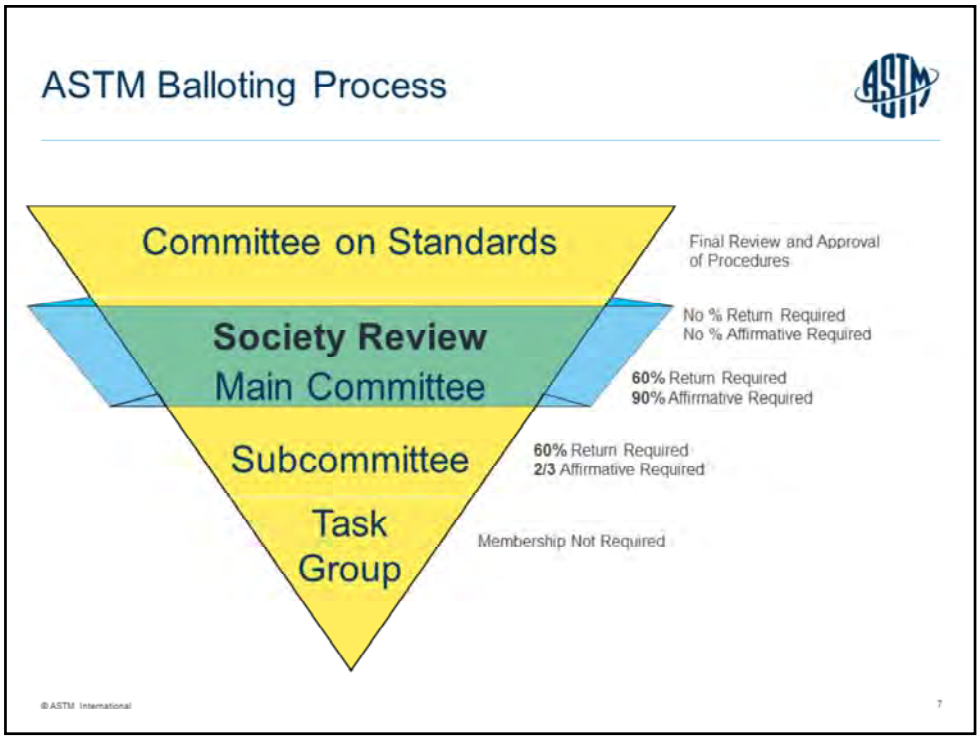


Further distinguishing the ASTM standards development process is its fair and balanced voting process. Simply stated, at ASTM International, all members have an equal vote and equal voice in the development of technical standards. Fairness is further ensured through balanced participation among producers, users and general interest members of an ASTM standards writing committee.

Openness, transparency and a balanced, consensus process are the hallmarks of the ASTM system and have contributed to the quality, integrity and worldwide acceptance of ASTM standards for over 110 years.

Technical Committee Organization

- Technical Committees form to address specific industry needs
- Subcommittees are established to address subsets of specialized subject matter
- Subcommittees organize their expertise into Task Groups to write standards



Member participation from around the world is what makes ASTM a truly international standards development organization. ASTM opens its doors to all interested individuals and organizations from around the globe that want to participate in the Society's consensus process for standards development. This process ensures that all interested parties have an equal vote in determining a standard's content. ASTM's enduring philosophy of consensus without borders helps make ASTM responsive and relevant to the needs of the global marketplace. As a result, more than 40 percent of ASTM's standards are sold outside the United States.

Strengths of ASTM's Standards Development System

Global Solutions to Common Problems

- ASTM membership is open to direct participation globally
- Over 7,700 ASTM standards are referenced or adopted in over 75 countries

Known for Technical Quality and Market Relevance

- ASTM process keeps the science in, and politics out

Solve Problems Expert to Expert

- Collaborate in an open, transparent and inclusive process

ASTM International - Wide Range of Consumer Related Activities

- D01 Paint
- D10 Packaging
- D11 Rubber
- D12 Soaps
- D13 Textiles
- F08 Sports Equipment
- F09 Tires
- F04 Medical Devices
- F11 Vacuum Cleaners
- F14 Fences
- F15 Consumer Products
- F24 on Amusement Rides and Devices
- F27 Snow Skiing

ASTM International Committee F15

- Consumer Product Safety Standards
- Founded in 1972 at the request of US Consumer Product Safety Commission
- 1000 members
- 100 standards
- 60 subcommittees

Keeping everyday products safe

U.S. Consumer Product Safety Commission

A SAFER GENERATION OF CRIBS

New Federal Requirements

F15 Subcommittees

02 Lighters
03 Bathtubs
06 Air Rifles
09 Home Playground
10 Flammable Liquids
11 Bed Rails
16 High Chairs
17 Strollers
18 Cribs
19 Infant Bedding
20 Bath Seats
21 Carriers/Swings
22 Toys
24 Children's Jewelry
28 Pool Covers
29 Public Playground Equip.
30 Bunk Beds
31 Plastic Containers
32 Innersprings
33 Plastic Furniture
36 Soft Contained Play
37 Drawstrings

More F15 Subcommittees

38 Window Guards
39 Beanbag Chairs
41 Fun Karts
42 Furniture Tip-Over
43 Soccer Goals
44 Play – Under Two
45 Candle Products
46 Fire Suppression Towels
47 Fire Ladders
49 Pool Safety
50 Comm. Changing Tables
51 Safety Vacuum Release Systems
52 Scooters
53 Firearm Locking Devices
55 Firearm Security Containers
56 Shopping Carts
57 Commercial Cribs
58 Powered Scooters and Pocket Bikes
59 Children's Folding Chairs
60 Portable Pools
61 Constant Air Play Equipment for Residential Use
63 Inflatable Air Mattresses
66 Crib Mattresses
70 Adult Safety Products
71 Laundry Packets

F15 Mission

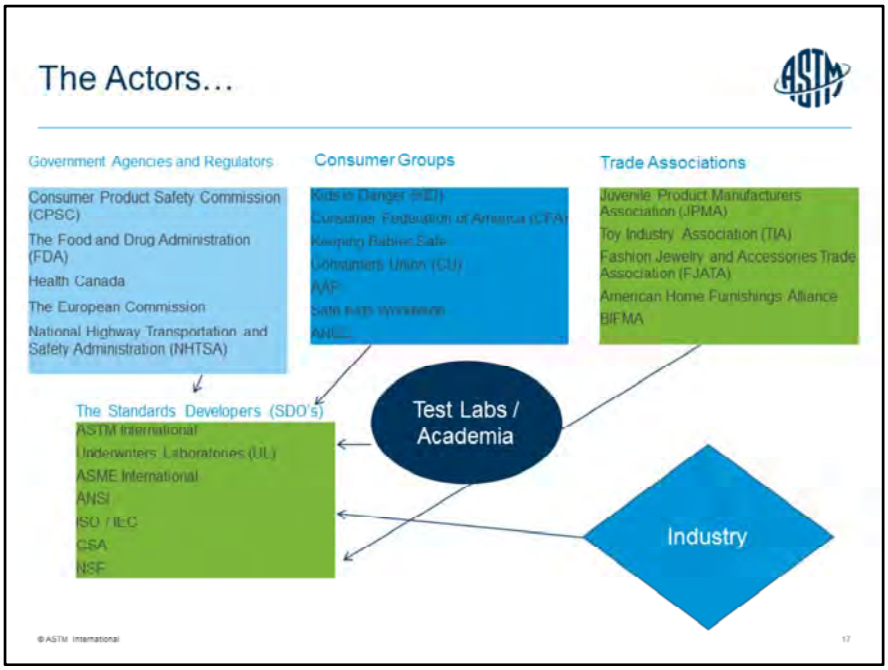
- Development of voluntary consensus standards
- Risk assessment standards (versus hazard assessment)
- Performance focused (versus design specific)

How ASTM Committee F15 Works

- Participants include consumer advocates, government agency representatives, consultants, manufacturers, lawyers, educators and testing laboratories.
  - If not for the standard-setting process, these diverse interest groups rarely meet outside of a courtroom or legal proceeding.
- Standards meetings are informative and candid. Attendees share their experiences and knowledge to create better standards and, ultimately, better products.
- Consumer Product Safety Commission (CPSC) incident data – including the National Electronic Injury Surveillance System (NEISS) data – helps to drive the process.
  - Data provided to each of the relevant ASTM subcommittees on patterns of injuries involving specific products.
  - These patterns of injuries assist the subcommittees in determining what direction to take in the development of a new standard, or a revision to a current standard.

Lots of ABC's to get to a 'Safe Product'

- The product safety landscape is complex
- There are many actors, each with unique and changing roles
- Key considerations
  - Type of product
  - Intended market
  - Hazards


The Actors…
Government Agencies and Regulators
Consumer Product Safety Commission (CPSC)
The Food and Drug Administration (FDA)
Health Canada
The European Commission
National Highway Transportation and Safety Administration (NHTSA)
Consumer Groups
Kids in Danger (KID)
Consumer Federation of America (CFA)
Keeping Babies Safe
Consumers Union (CU)
AAP
Safe Kids Worldwide
ANEC
Trade Associations
Juvenile Product Manufacturers Association (JPMA)
Toy Industry Association (TIA)
Fashion Jewelry and Accessories Trade Association (FJATA)
American Home Furnishings Alliance
BIFMA
The Standards Developers (SDO's)
ASTM International
Underwriters Laboratories (UL)
ASME International
ANSI
ISO / IEC
CSA
NSF
Test Labs / Academia
Industry
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- Building on the work of our founders in the early rail industry – ASTM's standards ensure safety, quality and reliability.
- But progress never stops. We're constantly responding to new challenges, new technology and new markets – by developing new standards and enhancing established ones.
- We base our rigorous development process on voluntary consensus. This gives everyone an opportunity to participate in creating and defining a standard.
- It also ensures that our standards are effective and relevant across the diverse markets we serve.
- Our standards help everyone: consumers, businesses, manufacturers, innovators and governments.
- They underpin contracts, laws and regulations. They support established and emerging economies – and ultimately – free and fair global trade.

Standardization & Its Role in Consumer Protection

- Consumer product safety standards are the most effective method to improve product safety and reduce injuries.
- Improved safety standards affect all products in a given category, not just those made by one manufacturer.
- Standards have a greater impact than recalls since eliminating the unsafe product before it is produced is most effective in improving product safety.
- Good regulations are developed in a transparent manner, with input from all affected stakeholders.
- US Congress recognizes this extraordinary effectiveness and requires that the Consumer Product Safety Commission (CPSC) rely on voluntary/consensus standards.

CPSC Mission

Ensure that Consumer Products are Free of Unreasonable Safety Hazards by:

- Facilitating the development of effective voluntary standards
- Issuing and enforcing mandatory standards or banning products if no feasible standard is possible
- Initiate recalls or corrective action of products that pose potential risk for serious injury or death
- Conduct research on potential hazards
- Inform and educate consumers
- Encourage industry to implement best practices to ensure safe products

Outside of Regulation

Public/Private Partnership

- CPSC staff provided technical support or was otherwise engaged in the development of voluntary safety standards for 70 different products
- Participate in numerous ASTM committees
- Provide incident data and contribute to technical solutions
- Annual report of standards activities available at http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2016/VoluntaryStandardsActivitiesFY2016MidyearReport-May232016.pdf

WTO Good Regulatory Practices

- Regulatory efforts must focus on outcomes (i.e., the protection regulations provide, not on the specific requirements or process), and should not be more restrictive than necessary to achieve the desired result
- Good regulations are developed in a transparent manner, with input from all affected stakeholders
- Regulatory actions should, wherever possible, be based on solid scientific data, and should be risk-based
- Standards should meet societal and market needs and should not act as barriers to trade, even if this is unintentional

WTO Good Regulatory Practices (cont'd)

- Existing international standards should be considered and evaluated for their ability to achieve desired regulatory outcomes before other approaches are considered
- Costs of regulation to business and consumers must be weighed against the benefits achieved
- Benefits (consumer protection and other benefits, facilitation of trade, openness of markets) of alignment with existing standards either globally or regionally must be weighed against the perceived incremental benefits of adopting a differing standard

Everyone Plays an Important Role

The Consumer Product Safety Improvement Act of 2008 (CPSIA)

- Passed in response to high-profile product recalls in 2007 & 2008
  - Lead paint in children's toys
  - Powerful magnets falling out of toys
  - Dangerous cribs and infant sleep environments

- Major Provisions:
  - Create a publically searchable Web-based database of reports of injury, illness or death (or risk of)
  - Mandated that CPSC issue mandatory standards for durable infant nursery products
  - Set new, stringent limits on lead in the paint of consumer products and on the substrate of children's products
  - Required third-party testing and certification on certain children's products
  - Authorized more direct engagement with foreign partners
  - Prohibits the sale of recalled products
  - Requires Tracking Labels on Children's Products
  - Significantly increases civil penalties and enhanced criminal penalty provisions

Section 106 of CPSIA - Toy Safety Standards

Section 106 - ..., the provisions of *ASTM International Standard F963–07 Consumer Safety Specifications for Toy Safety* (ASTM F963), as it exists on the date of enactment of this Act...

One Hundred Tenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and eight

An Act

To establish consumer product safety standards and other safety requirements for children's products and to reauthorize and modernize the Consumer Product Safety Commission.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Consumer Product Safety Improvement Act of 2008".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

ASTM F963 Facts

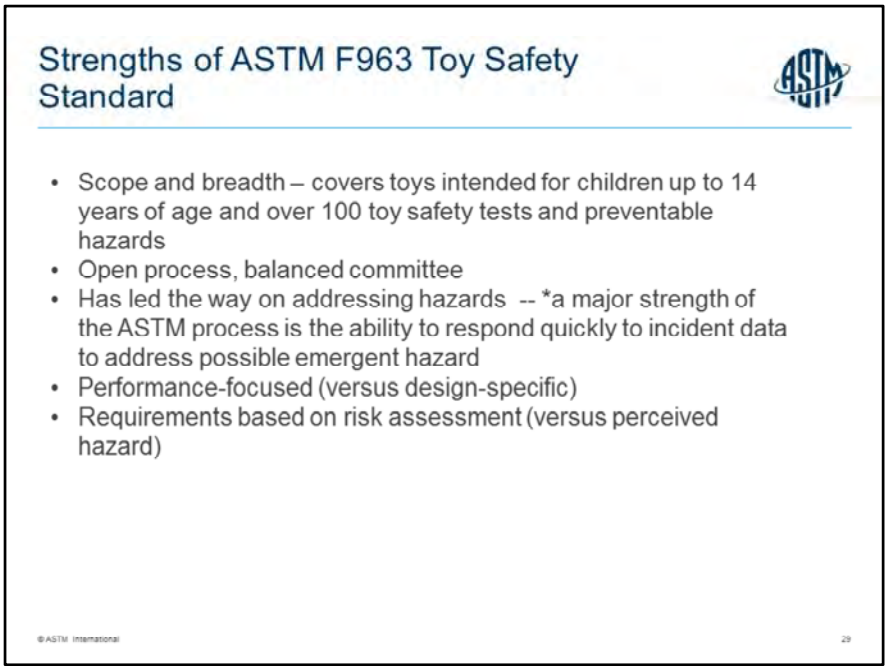
- Against a backdrop of minimal US federal regulation of toy safety, the US toy industry created the first comprehensive voluntary safety standard in the 1970s.
- The successor to this standard is ASTM F963, published by ASTM International and administered as a consensus standard
- ASTM F963 is frequently revised to address emerging hazards; *A major strength of the ASTM process is the ability to respond quickly to incident data indicating a possible emergent hazard*
- ASTM F963 has historically led the way on addressing hazards, subsequently sharing this information with CEN and ISO-examples where this has occurred are magnets, hemispherical shape impaction hazards, jaw entrapment, and cup-shaped toys

US CPSC Chairman awarded the ASTM F15.22 the prestigious Safety Commendation in 2013

Requirements of ASTM F963 -- SCOPE

ASTM F963 details comprehensive requirements in the following areas:

- Mechanical/Physical/Material Quality
- Electrical
- Flammability
- Toxicology
- Microbiological cleanliness/preservative effectiveness
- Labeling

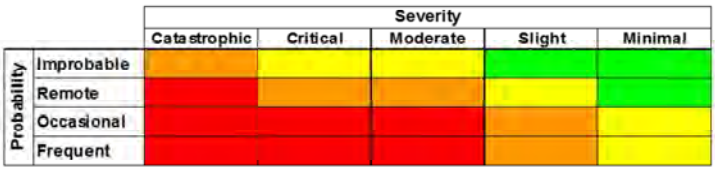


****The ASTM Toy Safety Standard -- adopted and emulated by other countries and regions of the World.**

<u>Some of the Strengths</u> :

1. **Its Scope and Breadth** – toys intended for children up to 14 years of age and over 100 toy safety tests and preventable hazards including requirements for --- small parts and sharp edges ---- other ingestion and impaction hazards ---- material content, cleanliness and quality ---- flammability, projectiles, and others
2. **Its Open** process, and **balanced** committee, which contribute to the resources of input, transparency and credibility – of the standard.
3. **Historically, the ASTM standard has led the way on <u>addressing emerging hazards</u> -- *<u>A major strength of the ASTM process is the ability to respond quickly to incident data to address possible emergent hazards</u>***
   - *** <u>AND THEN SHARES this info</u> with its counterparts, such as in other standards bodies – such as CEN and ISO (European ISO standards)**
   - ***** THIS IS CONSISTENT WITH THE INDUSTRY'S COMMITMENT TO CONTINUALLY REVIEW AND REVISE STANDARDS TO KEEP PAVE WITH INNOVATION IN TOYS – AND TO ALIGN STANDARDS WHEREVER POSSIBLE.**
   - **** Some recent examples of emerging issues identified and addressed within ASTM*** – magnets in toys, hemispherical and spherical-shaped impaction hazards, jaw entrapment, cup-shaped toys, etc.)
4. **US CONGRESS RECOGNIZED THE EFFICACY OF ASTM F963 by making it a mandatory US federal standard as part of Consumer Product Safety Improvement Act of 2008**

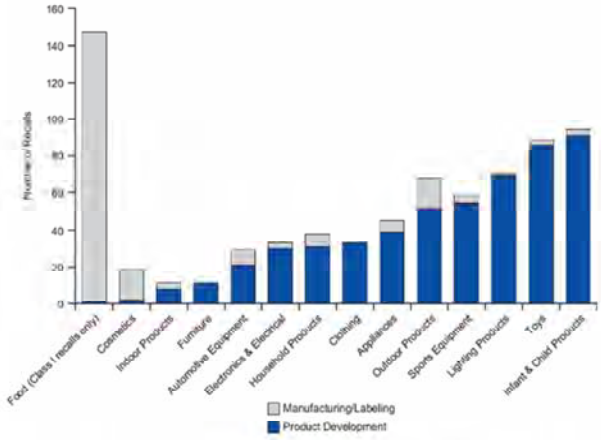
Risk Management Strategy – Risk Tolerance



- Design Out the Potential Hazard
- Protect or Safeguard Against the Hazard
- Provide Effective Warnings or Instructions
- Accept the Risk Based on an Educated and Informed Fact-Based Decision

Root Cause of Product Recalls

Figure 4: Number and Root Cause of Product Safety Recalls Across Consumer Products Categories (1999-2001)



Source: PRTM White Paper, © PRTM 2002

Design Failure Modes Effect Analysis

A DFMEA process follows these steps:

- Review the product in detail to understand functions
- Brainstorm potential foreseeable uses and failure modes
- List potential effects or hazards of each use and failure mode
- Classify severity, probability of occurrence and probability of detection of each hazard and failure mode
- Determine design solutions or manufacturing control points based on identified failure modes
- Make risk decision based on findings and business needs

There are several tools recommended to conduct this analysis that also make up the Risk Assessment Process

Risk Assessment Process

Data Analysis

There are a variety of sources available to obtain data:

- U.S. CPSC Recall Database
- EU RAPEX Recall Database
- U.S. CPSC NEISS Injury Database
- U.S. CPSC Death Certificates
- Consumer Complaint Database
- Consumer Studies

Risk Assessment Process

Hazard Identification and Analysis

There are key steps to perform an effective hazard analysis

- Research any regulatory or industry standards associated with product or products with similar characteristics to understand the known hazards (also understand deficiencies in standards)
- Research the anatomy associated with the hazard (which body parts are affected and what is unique with the body part)
- Understand the mechanism of the hazard (how does it occur)
- Study injuries associated with the hazard to better understand mechanisms, consumer behaviors that led to injury and potential severity
- Determine the general and specific product characteristics that contribute to the above variables

Keeping Pace With Change

Cooperation helps with challenges

- Global Harmonization
- Territoriality
- Regulatory Conflicts / Reciprocity
- Duplication of Effort / Few Resources
- Marketplace Confusion
- Emerging Hazards

– It's vital that ASTM stay relevant and fully aligned to user needs. All standards are reviewed every 5 years, but, in fast-moving sectors, it's more frequent than that.
– We also work hard to constantly improve our own working methods.
– Our standards development process is flexible, transparent and built on consensus.
– It's backed by powerful tools and technologies that enhance global connectivity.
– These systems give members the freedom to be in instant contact, to share thinking and to review and develop standards more quickly.
– This reinforces our reputation for timely as well as relevant standards.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