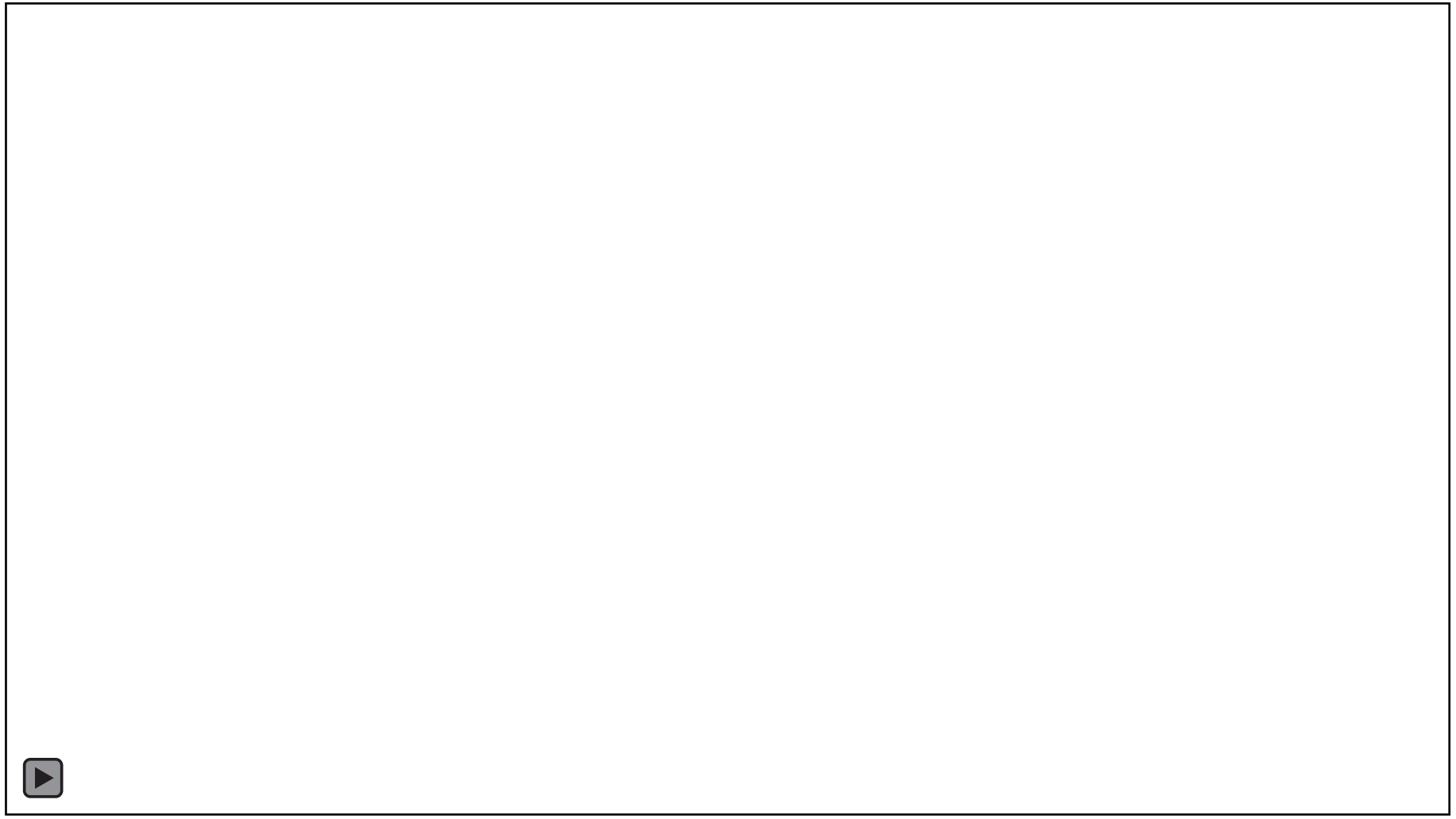
The slides used in this presentation are intended to be used in an event with verbal elaboration by a knowledgeable presenter. The slides highlight key U.S. product safety requirements for discussion. The text is not a comprehensive statement of legal requirements or policy and should not be relied upon for that purpose. Moreover, with the passage of time, it may not reflect the latest information. You should consult official versions of U.S. statutes and regulations, as well as published CPSC guidance when making decisions that could affect the safety and compliance of products entering U.S. commerce.

Video: Welcome to the 2021 CPSC Podcast Series – Enhancing the Safety of Emerging Technology Through Risk Assessment: Wearables



United States
Consumer Product Safety Commission

Podcast Series 2021

Enhancing the Safety of Emerging Technology Through Risk Assessment: Wearables

This presentation was prepared by CPSC Staff. It has not been reviewed or approved by the Commission and may not reflect its views.

Biographies

Sylvia Chen
U.S. Consumer Product Safety Commission
Program Manager for East Asia and Pacific
Office of International Programs

Sylvia Chen is responsible for managing the Commission's bilateral and multilateral programs related to consumer product safety in Australia, Japan, Korea, Taiwan, and New Zealand. She also supports the CPSC's work with China. Since she joined the CPSC in 2008, Sylvia has been working with product safety regulators, industry organizations, manufacturers, exporters, buyers, and other sourcing professionals to provide them with guidance and technical support in understanding U.S. requirements, in particular, the latest requirements for consumer products. To that end, she has organized or coordinated many of the agency's international education and outreach activities.

Sylvia has a Bachelor of Arts degree in English and American Literature from Peking University. In 1991, she graduated from The Ohio State University with a Master's degree in East Asian Studies.

$1 Trillion

Deaths, injuries, and property damage from consumer product incidents cost the nation more than $1 trillion annually.[1]

The US CPSC is a federal government agency charged with protecting the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction.

[1] https://www.cpsc.gov/s3fs-public/FY2019PBR.pdf

CPSC is committed to protecting consumers from products that pose a fire, electrical, chemical, biological, or mechanical hazard.

CPSC's work to improve the safety of the more than 15,000 types of consumer products in its jurisdiction - such as toys, cribs, power tools, cigarette lighters, textiles, and household chemicals – has contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.

CPSC's Podcast Series 2021

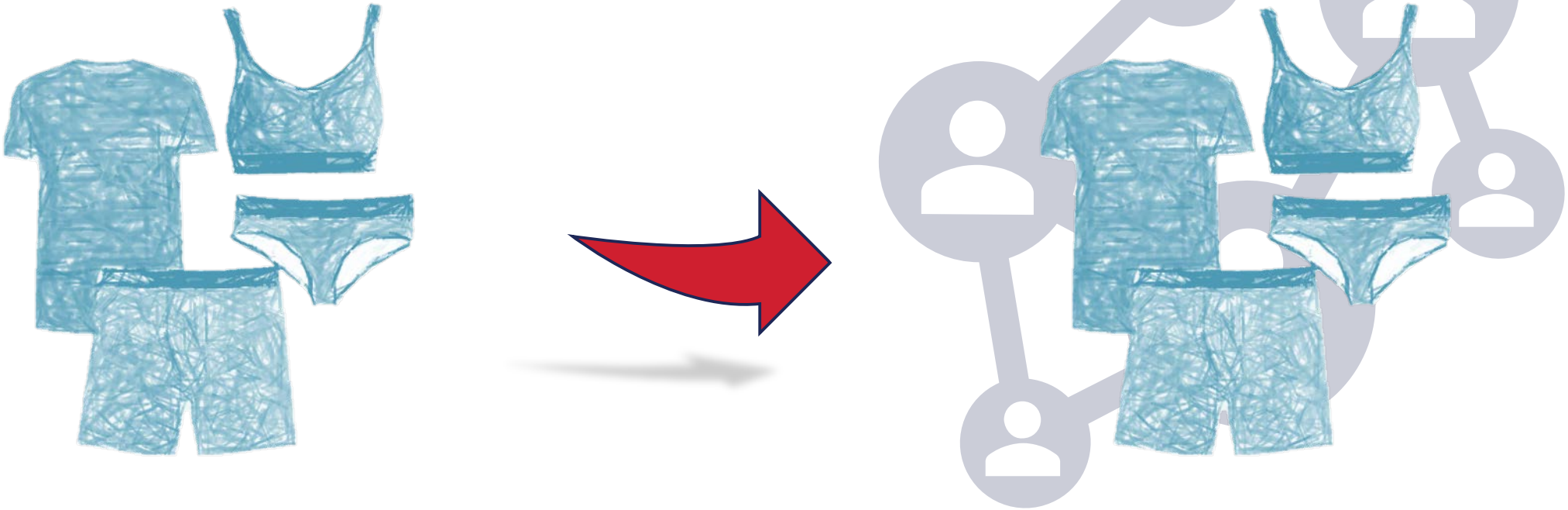
Podcast	Topics
#1	Overview of Children's Sleepwear Requirements
#2	Enhancing the Safety of Emerging Technology through Risk Assessment: Wearables
#3	Overview of Battery Safety Requirements
#4	Overview of Gates and Enclosures Requirements
#5	Overview of Consumer Safety and Micromobility Devices
#6	Overview of Cribs and Play Yards Requirements

"Questions on this Presentation? Send an email to CPSCinChina@cpsc.gov"

Enhancing the Safety of Emerging Technology through Risk Assessment: Wearables

Connected Products

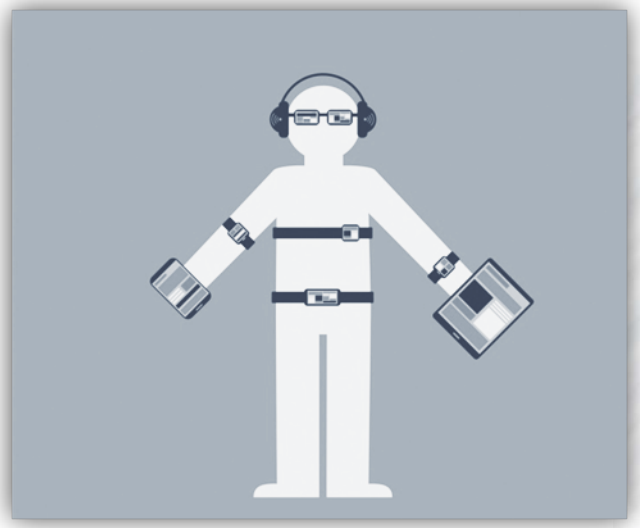
"—any consumer device or physical object that is capable of connecting to the internet or other network directly or indirectly and is assigned an internet, Bluetooth, or other communication protocol address or identifier." ASTM F3463.

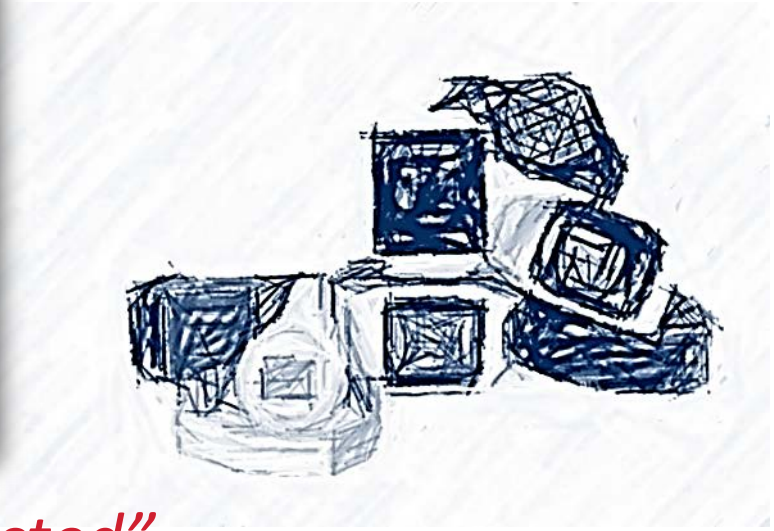


What is Wearable Technology?

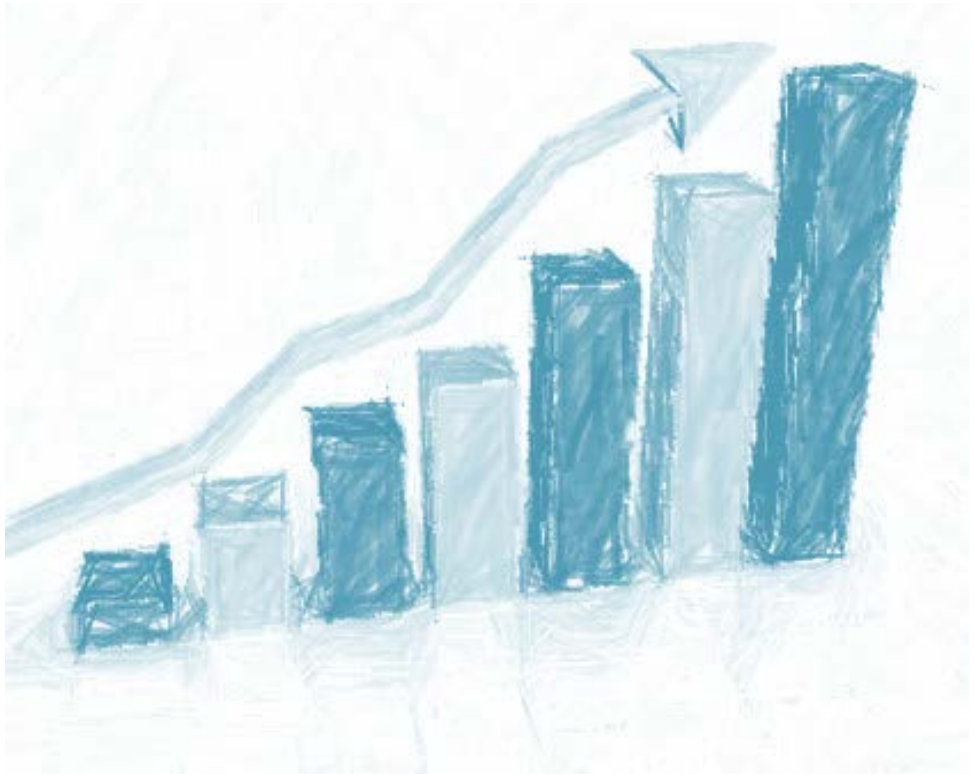
"Smart"

"Worn on or in the body"





"Connected"



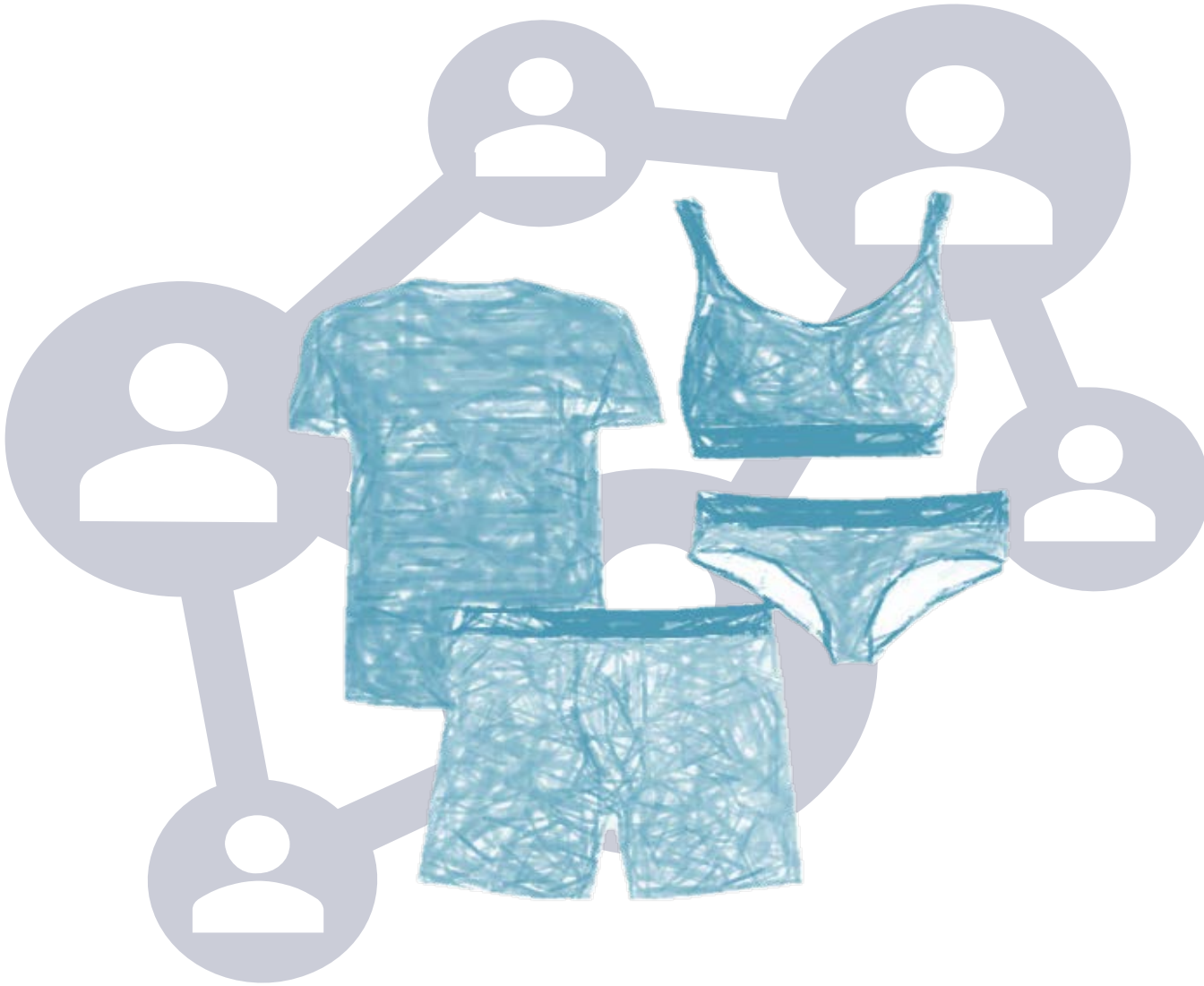
New Product Trends

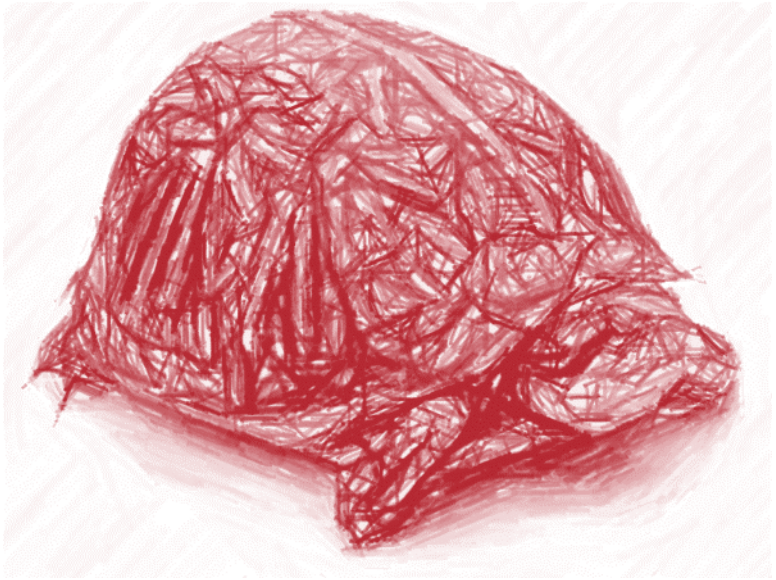
Wearables

According to a recent forecast of the market by IDTechEx:

“The increasingly diverse market for wearable devices will reach over $150 billion annually by 2027.”

https://www.idtechex.com/research/reports/wearable-technology-2017-2027-markets-players-forecasts-000536.asp





The Pace of Innovation Versus Regulation

Regulatory Landscape: *Device* Versus *Product*

Definition of a Medical Device

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Risk?

According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- **intended for** use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- **intended to** affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Consumer Product Safety Commission

Consumer Product Safety Act, 15 U.S.C. § 2051:

(1) to protect the public against unreasonable risks of injury associated with consumer products;

(2) to assist consumers in evaluating the comparative safety of consumer products;

(3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and

(4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

What is a consumer product? 15 U.S.C. § 2052:

any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise;

CPSC does not regulate medical devices

**Note: This is a general definition that has numerous exclusions.*

The CPSC regulatory process is initiated by a vote of the Commission or a petition from an interested party.

CPSC statutes specify a consumer product safety rule shall not be issued unless:

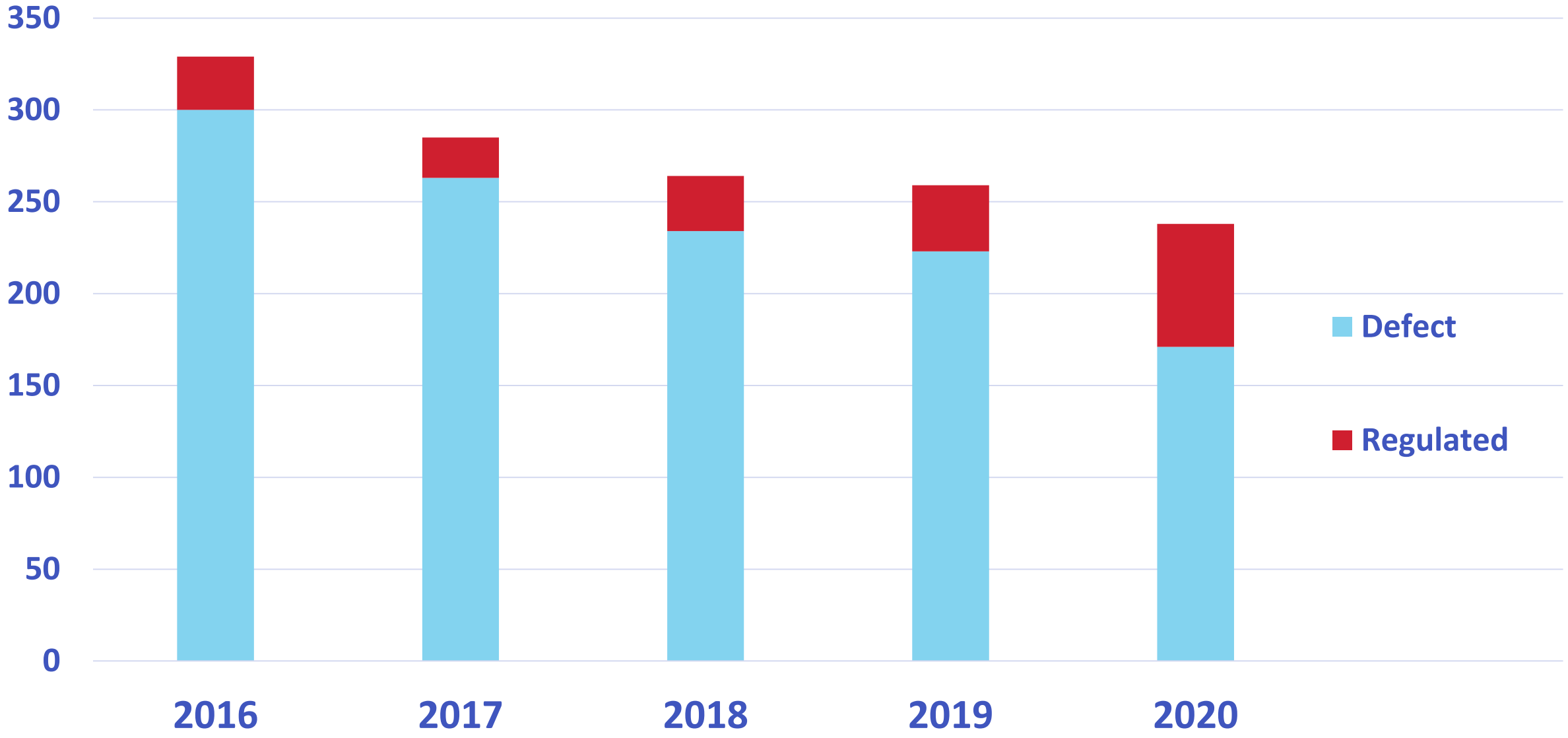
- a current industry consensus standard is not likely to adequately reduce the risk of injury

OR

- there is not likely to be substantial compliance with the consensus standard

CPSC Recalls

Defects vs. Regulated Products



Risk Assessment Strategy

Risk Assessment

Risk is a combination of three elements:

- The hazard scenario(s) leading to a potential injury or death;
- The likelihood of the hazard scenario(s) occurring; and
- The consequence(s) in terms of hazard severity.

Risk Assessment Strategy: Steps

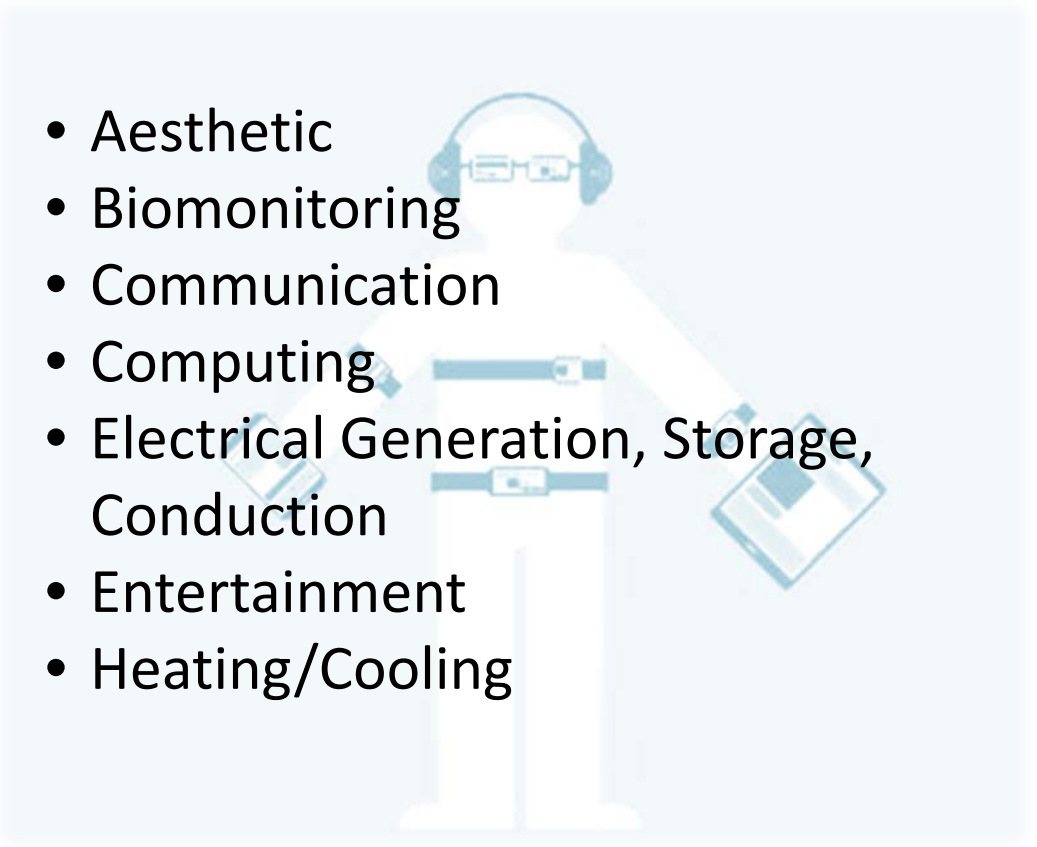
- Characterize Products
- Categorize Hazard(s)
- Identify Hazard Patterns and Consequences
- Determine the Potential Risk

Risk Assessment: Characterize Product

- What is the purpose of the product?
- Who is the intended user?
  - General use or potential vulnerable population (ex. children)?
- Are there alternate foreseeable uses beyond those intended?
- How will the product be marketed and sold?

Risk Assessment: Categorize Hazard

What is the product's function?



- Aesthetic
- Biomonitoring
- Communication
- Computing
- Electrical Generation, Storage, Conduction
- Entertainment
- Heating/Cooling

Risk Assessment: Categorize Hazard

What is the location where the product is used?

- Arm
- Body (General)
- Ear
- Eye
- Finger
- Fingernail
- Foot
- Genitals

- Hand
- Head
- Leg
- Mouth
- Neck
- Skin
- Waist
- Wrist
- Other/Multiple

Risk Assessment: Categorize Hazard

What types of exposure does the product present?

- Biological (post-use biological exposure, mold, bacteria, particles)
- Electrical (shock, electroporation, electromagnetic radiation)
- Inorganic and organic compound (chemicals, metals, particles)
- Light (light, radiation)
- Magnetic field (magnetic)
- Sonic (noise)
- Thermal (fire, overheating)
- Vibration
- Other

Risk Assessment: Identify Hazard Patterns and Consequences

- Review data
  - Product
    - Same product
    - Analogous product
  - Hazard
    - Consequences
      - Include range of outcomes, not just average
      - Severity
    - Likelihood
      - Probability

Risk Assessment: Determine Product Risk

- Risk = likelihood x consequence for the scenario
- Higher risk products should be given the most scrutiny
  - Example: Children's products
  - Example: Products that work in direct contact with skin
- Are there ways to reduce elements that increase risk?
  - Can components, location, or designed usage change to make a product less risky?

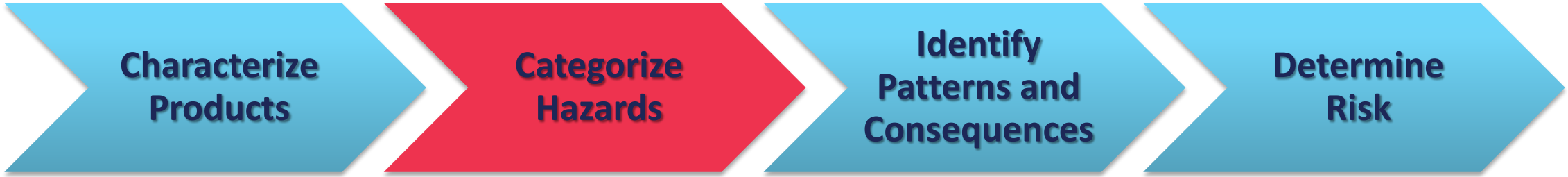
Note: The same risk mitigation strategy may not be appropriate for all products even if they are in the same product class!

Case Study: Connected Apparel

- What is the purpose of the product?
  - ➢ Provide comfortable, fashionable exercise apparel that is instrumented to provide data to the user through connection to a smartphone app
- Who is the intended user?
  - Adults, ages 18-65, athletes
- Are there alternate foreseeable uses beyond those intended?
  - No other intended uses, but instrumentation or data might be used for other purposes
- How will the product be marketed and sold?
  - Company website only, using targeted advertising in fitness journals and websites and sports personalities as spokespeople

Characterize Products → **Categorize Hazards** → **Identify Patterns and Consequences** → **Determine Risk**

- What is the function of the product?
  - Biometrics (data gathering and reporting), protection of body (apparel)
- Where is the product located during use?
  - Directly against skin, instrumentation is insulated
- What are the potential exposure hazards?
  - Electrical, thermal, chemical, flammability

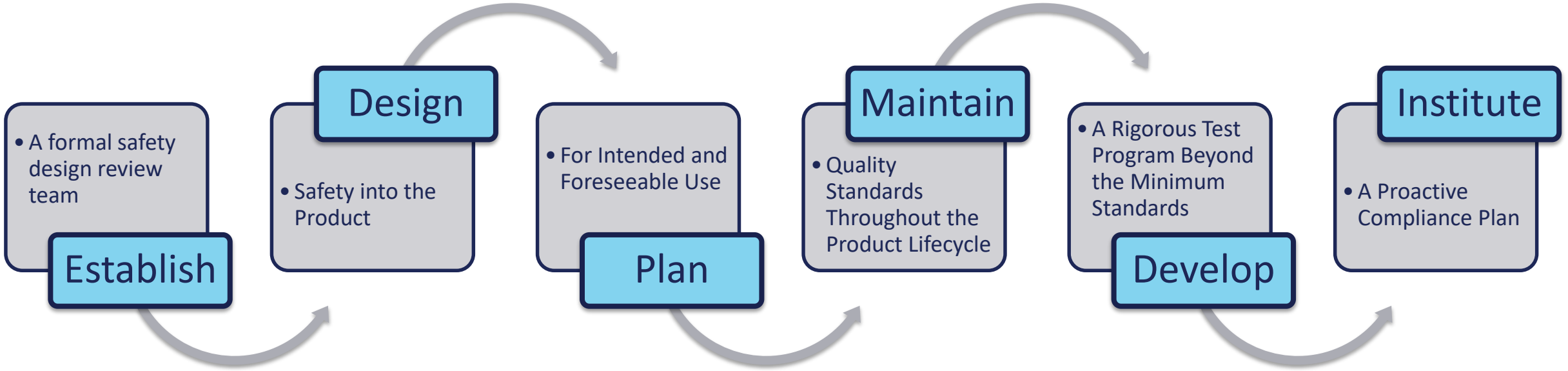


- Data Sources
  - Competitors' products with similar attributes
  - In-house and commercial laboratory testing
  - "Beta" testing with small user group
- Hazard Patterns and Consequences
  - Patterns
    - Electrical (performance failures from laundering, but potential shock hazard)
    - Thermal (burns from failure of connectors for energy source)
    - Chemical (limited number of skin rashes from chemicals in fabric finish)
  - Consequences
    - Low to medium

- Risk = Low/Medium
- Potential risk mitigation strategies
  - Change connector design (to address electrical and thermal hazard)
  - Change chemical finish (to address chemical hazard)
- With proposed strategies in place,
  - Risk = Low

Specific Product Requirements

- CPSC Requirements
  - GCC
  - Clothing Textiles Flammability (16 CFR part 1610)
  - Any applicable industry consensus standards for safety (electrical)
- Other Considerations
  - Impact of wear on safety performance (laundering, abrasion, etc.)
  - Interaction with skin (sensitivity)
  - Other???



Best Practices

Establishing a Safety Culture

CPSC Activities on Enhancing Safety of Consumer Products with Emerging Technologies

CPSC Activity

New Products and Emerging Hazards

2014
- Recall of wearable consumer product

2017
- *Potential Hazards Associated with Emerging and Future Technologies*

2018
- Commission Public Hearing on IoT and Consumer Product Hazards

2019
- CPSC Interagency IoT Working Group
- *Status Report on the Internet of Things (IoT) and Consumer Product Safety*
- ASTM F15.75 Connected Products *DRAFT Standard Guide for Ensuring the Safety of Connected Products*

2020
- NIST-CPSC IAA *Building CPSC's workforce of tomorrow: Cybersecurity and Safety of Internet Connected Consumer Products*
- New CTO hired to focus on AI in consumer products

Questions?

Submit questions in English or Chinese to this podcast:
CPSCinChina@CPSC.GOV

Resources

Chinese Resources at cpsc.gov

https://www.cpsc.gov/zh-CN/Business--Manufacturing/Business-Education

Chinese Resources at cpsc.gov

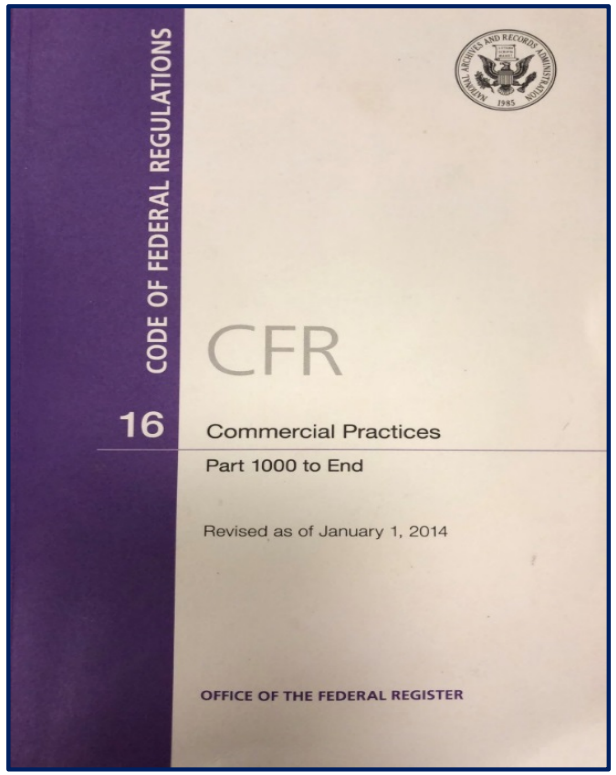
https://www.cpsc.gov/s3fs-public/HandbookforManufacturingChinese.pdf (中文版本)

https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_handbookenglishaug05.pdf (英文版本)

https://www.cpsc.gov/s3fs-public/THE%20REGULATED%20PRODUCT%20HANDBOOK_050613%20CHN%20Final_0.pdf (中文版本)

https://www.cpsc.gov/s3fs-public/RegulatedProductsHandbook.pdf (英文版本)

Chinese Resources at cpsc.gov



CFR: Commercial Practices
https://www.govinfo.gov/content/pkg/CFR-2017-title16-vol2/pdf/CFR-2017-title16-vol2.pdf (英文版本)

CPSC Laboratory Manuals:
https://www.cpsc.gov/s3fs-public/Laboratory-test-manual-16-CFR-Part-1610-Ch.pdf?MhtbUWNy6jmOPx9b6f.ERrt.n.2n_d_h (中文版本)

https://www.cpsc.gov/s3fs-public/Flammability%20of%20Clothing%20Textiles%20Test%20Manual_1610.pdf (英文版本)

CPSC Business Resources

- Definition of children's product – 16 CFR Part 1200
- Certificates of conformity – 16 CFR Part 1110
- Third-party testing – 16 CFR Parts 1107, 1109, and 1112
- Tracking information – 15 USC § 2063(a)(5)
- Mandatory reporting requirements – 15 USC §2064

CPSC-Accepted
Laboratories Search Page:
www.cpsc.gov/LabSearch

REGULATORY ROBOT

Welcome to CPSC's Regulatory Robot!

http://business.cpsc.gov

Online tool designed specifically to help businesses comply with federal consumer product safety requirements.

Asks a series of guided questions, and based on the answers produces a downloadable (PDF) report.

Provides customized guidance with links to product safety regulations that may apply to the product and important information on labeling, certification and testing requirements.

Regulatory Robot

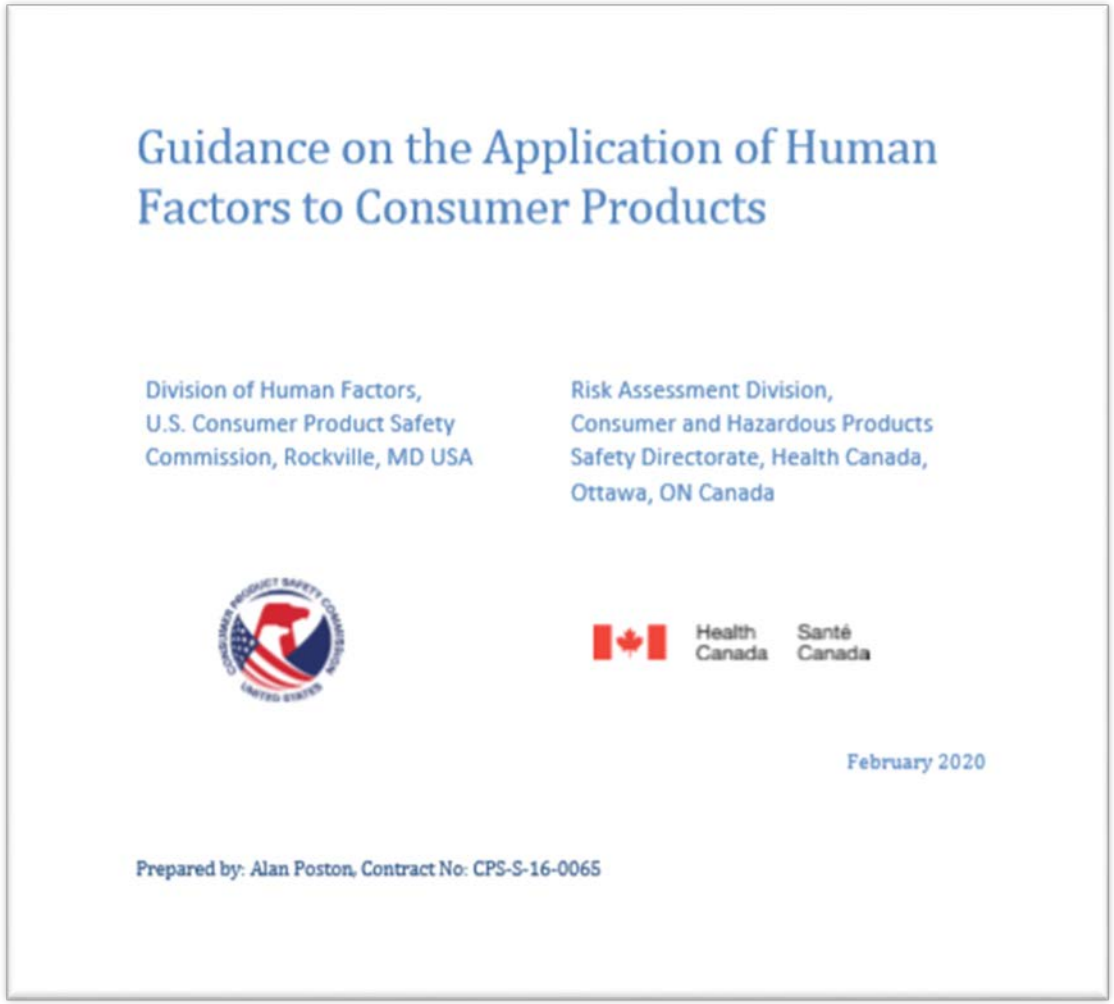
Regulatory Robot is a tool to help identify which requirements are applicable

- **<u>Does not</u> list details of requirements**

Some Relevant Industry Consensus Standards and Certifications

- International Society of Testing and Materials, American Section (ASTM)
  - D13.50 – Smart textiles
  - F3463 – Standard Guide for Ensuring the Safety of Connected Consumer Products
- American Association of Textile Chemists and Colorists (AATCC)
  - https://www.aatcc.org/testing/emerging/
- Institute of Electrical and Electronics Engineers (IEEE)
  - International Roadmap for Systems and Devices https://irds.ieee.org/
- TÜV SÜD
  - https://www.tuv-sud.com/activity/testing/wearable-technology-wearable-device-testing-and-certification

Guidance on the Application of Human Factors to Consumer Products



Guidance on the Application of Human Factors to Consumer Products

Division of Human Factors,
U.S. Consumer Product Safety Commission, Rockville, MD USA

Risk Assessment Division,
Consumer and Hazardous Products Safety Directorate, Health Canada, Ottawa, ON Canada

Health Canada Santé Canada

February 2020

Prepared by: Alan Poston, Contract No: CPS-S-16-0065

https://cpsc.gov/s3fs-public/Human-Factors-Standard-Practice-Document-Final-ENGLISH-Feb03-2020_0.pdf?wAUEehL.VtEkpYpx8aLvYrTKqa9w0UMz

CPSC Data Resources

- National Electronic Injury Surveillance System (NEISS)
  - https://www.cpsc.gov/cgibin/NEISSQuery/home.aspx
- Consumer Product Safety Risk Management System (CPSRMS)
  - https://saferproducts.gov/