

Chemical & Environment Considerations in Product Safety

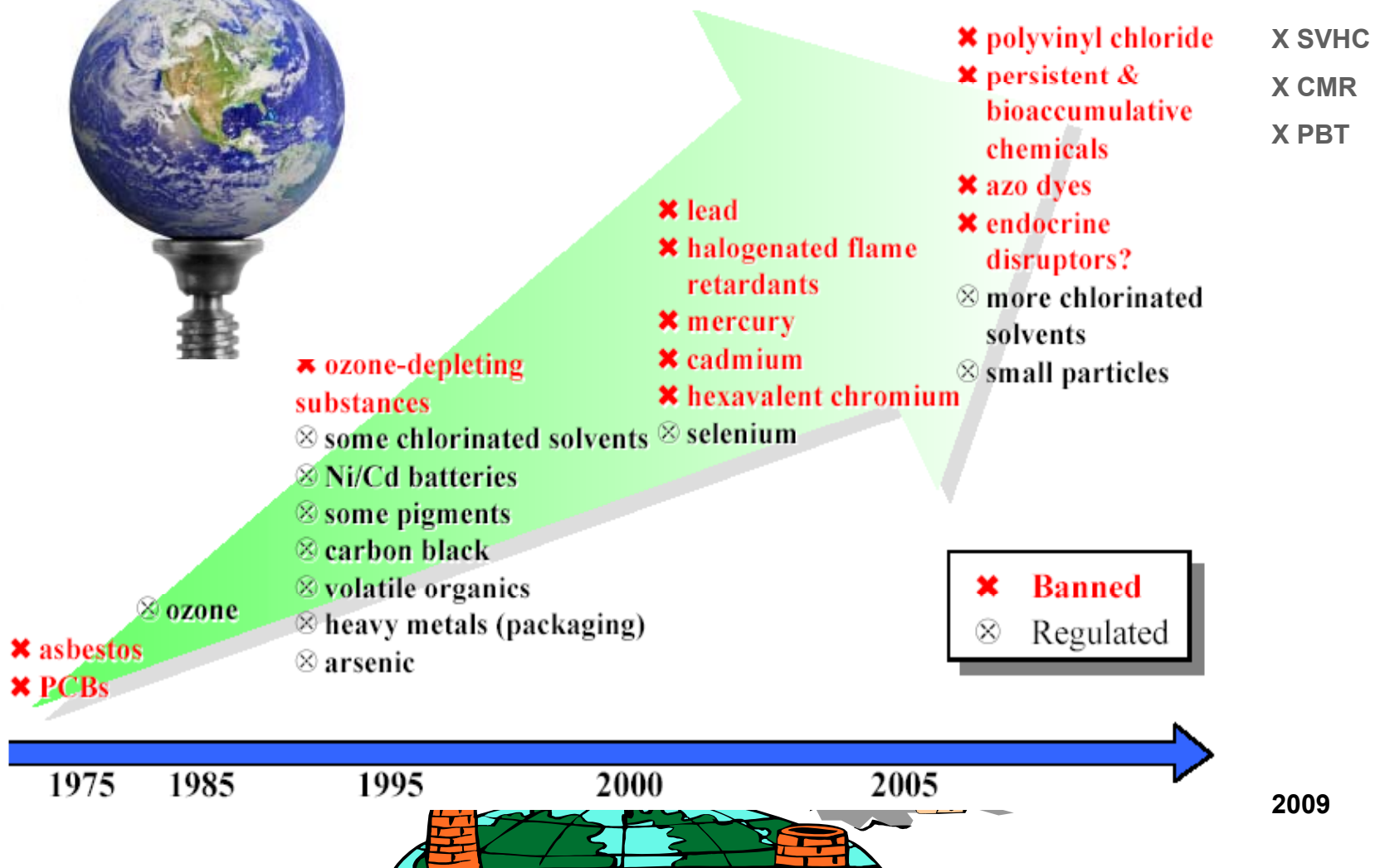
Chemical Safety Regulations – An overview

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WHEN YOU NEED TO BE SURE



Global Pressures on Chemical Users



Regulatory Drivers – US

- **US Federal Laws**
 - **U.S. Consumer Product Safety Commission (CPSC)**
 - **Environmental Protection Agency (EPA)**
 - **Kid-safe chemicals act? (US proposal)**
- **Federal Hazardous Substances Act**
- **Consumer Product Safety Improvement Act**
- **TSCA Reform**
 - **Kid safe Chemicals Act (proposed)**
 - **EPA chemical action plan**



Regulatory Drivers – US

■ US State Laws

- **CA Proposition 65**
 - **Kid-safe products act (Maine)**
 - **Various State laws**
 - **Similar laws Michigan, Massachusetts**
-
- **CA Green Chemistry**
 - **WA High Priority Chemicals List**
 - **Alternatives Assessment**
 - **Toxic Use Reduction**



Regulatory Drivers – EU Market

- EU Directive
 - Dangerous substances and preparations Directive
 - Market and Use Directive (76/769/EEC) e.g. Azo (2002/61/EC), Nickel release (94/27/EC), NP/NPEO (2005/53/EC)
 - Member State Laws
 - Swedish Product Safety Ordinance
 - EEA Norway POHS
-
- **REACH**
 - **Classification, Labeling and Packaging (CLP)**



Other Drivers

Green / ECO Labels

Brand Differentiation

- Business ethics and social responsibility
- Greater awareness of eco-brands
- Under pressure from consumer-protection advocates



EU
Eco-Label



Germany
Blue Angel



Japan
Eco-Mark



US
Green Seal



Nordic
Environmental Label



Okotex Standard 100
Eco-Label

The logo for SGS, consisting of the letters 'SGS' in a bold, sans-serif font. A vertical line is positioned to the right of the 'S', and a horizontal line is positioned below the 'S' and 'G', forming a partial crosshair.

Other Pressures CLIENT, PUBLIC, INVESTOR DRIVEN

The logo for Walmart, featuring the word 'WALMART' in white, uppercase, sans-serif letters. A white five-pointed star is placed between the 'L' and 'M'. The text is set against a solid blue rectangular background.

World's largest retailer

US \$375 billion sales

7,250 stores

“Provide to our customers affordable and effective products where all chemical ingredients are preferred for Mother, Child and the Environment”

Global Pressures: Investors



- Shareholder resolutions on chemicals (2006-08):
 - 2: Chemical makers
 - 10: Product makers
 - 16: Retailers
 - 28: Total
- Competitive advantage: who wins, who loses?

“Whack a Chemical”



vPvBT

PBT

CMRS

SVHCS

BFRs

Azo Dyes

Heavy Metals

The New York Times

Shift in Chemical Policy

- Prescriptive to Performance based
- Comprehensive and integrated approach towards toxic and hazardous substances
- Assessment based on inherent toxicity (hazards), uses, functions, and potential exposures
- Prioritize phase out higher toxicity chemicals first
- Safer alternatives
- Drive innovation through policy
- Benign by design

- **TSCA Reform: The Senate Safe Chemicals Act of 2010**
 - **House *Toxic Chemicals Safety Act of 2010***

- ❖ ***Chemical Substance (CS) definition***
- ❖ ***“CS” explicitly includes any CS in an article***
- ❖ ***Mixture” explicitly includes any mixture contained in or formed into an article***





TSCA Reform: Safety Determination of Chemicals

- Law would apply to “chemical substances”: “any organic or inorganic substance of a particular molecular identity,” with certain exceptions. Definition includes “articles.”
- All chemical substances ultimately subject to EPA determination of whether chemical meets an established safety standard.
- Burden is on manufacturers and processors to prove a chemical substance meets the safety standard.
- EPA must determine whether manufacturer/processor has satisfied the burden of proof generally within 180 days after submittal of required data.
- EPA’s determination whether the safety standard has been met would have to be supported by a risk assessment based on “best available science”.

TSCA Reform: New Chemical

Section 5 – New Chemicals

- Notice required with “new use”
- EPA determines if not reasonably anticipated to present risk or that safety standard has been met
- Upon EPA determination, commence production and notify EPA

Section 8 – Declarations and Information Gathering

- Declarations by manufacturers and processors
 - Within 1 year of enactment
 - Declarations every 3 years or whenever new information is available
- By rule or order, any person to submit records to assist EPA in safety determination
- Inventory listing

Section 4 – Testing

- Minimum Data Set (MDS)
 - hazard, exposure and use
 - may provide for varied or tiered testing
- Submit MDS
 - 18 months after listing on priority chemical list OR
 - 5 years after enactment
- May require additional testing as needed

Section 6 – Risk Management

- Within 18 months, EPA establishes priority list of at least 300 CS/Ms
 - EPA determines whether manufacturer or processor has shown safety standard has been met and adds additional CS/Ms to priority list;
- EPA can make the following findings:
 - More information is needed
 - Manufacturer can generate and submit information OR
 - EPA can determine CS/M does not meet standard
 - CS/M meets safety standard
 - EPA to post determination on public website
 - Certain conditions are needed to meet safety standard
 - One year to implement conditions
 - Manufacturers can request critical use exemption
 - EPA to post determination on public website
 - CS/M does not meet safety standard
 - One year to stop manufacture, processing and distribution
 - Manufacturers can request critical use exemption

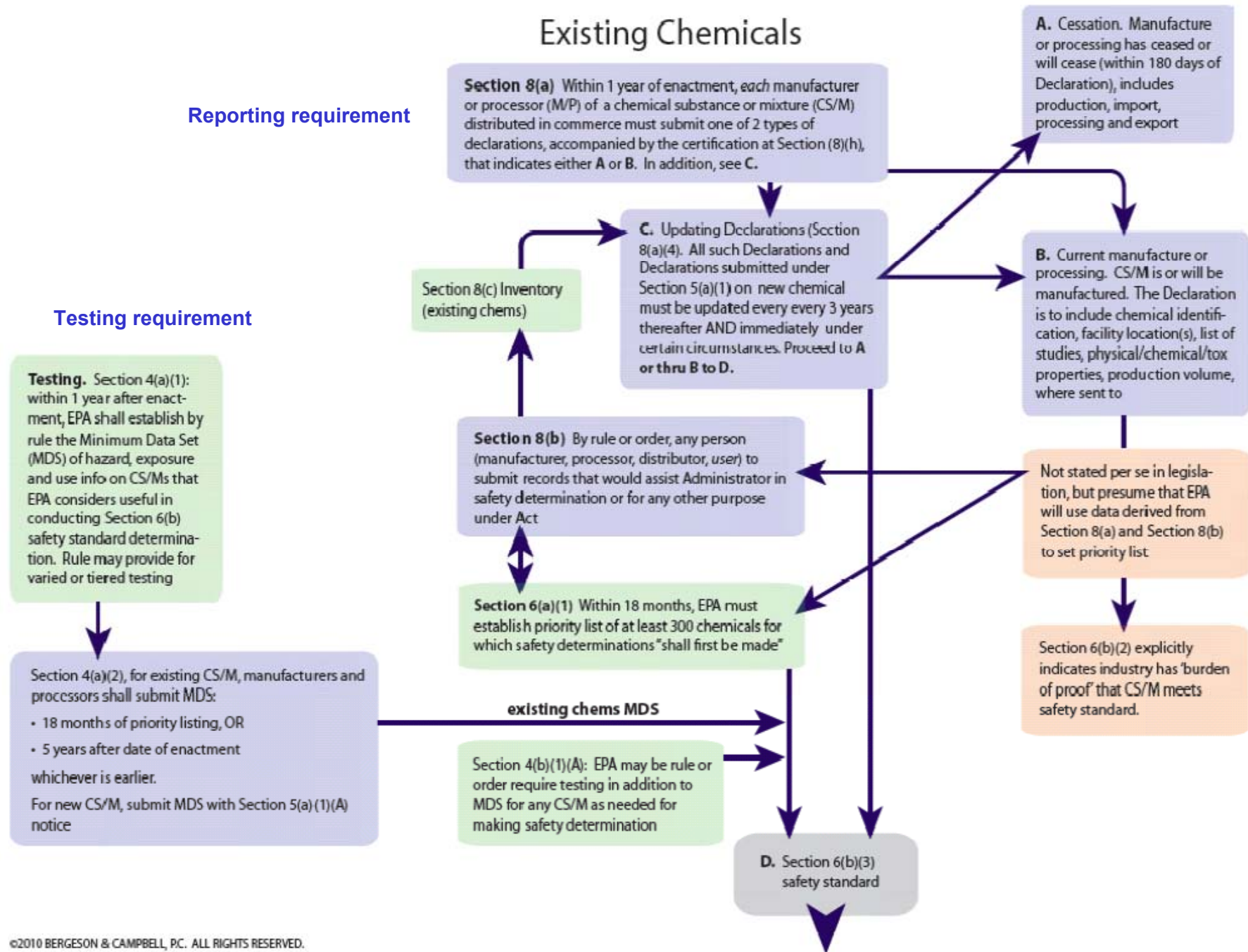
Section 6(b)(2) explicitly indicates industry has ‘burden of proof’ that Chemical Substance/ Mixture (CS/M) meets safety standard.

Process repeated every fifteen years, or with new information that impacts safety determination.

Existing Chemicals

Reporting requirement

Testing requirement





TSCA Reform: New Safety Standard

~~Original: Substantive “Unreasonable Risk”~~

Proposed: Reasonable Certainty of No Harm”

- Move to precautionary principle
- Burden on industry to prove chemicals are safe
- Authority to demand data and testing
- Priority list of chemicals with highest concern
- No movement since the bills were introduced
 - Highly political issue with the state of the economy
 - Federal legislation possible in 2011-2012

Stay Tuned!



State Safe Chemicals, Prioritization Legislation

- CA, ME, WA, OR, CT, MN (Starting 2012)
 - CA Green Chemistry Initiative
- WA State Children's Safe Product Act (CSPA)

Source: www.chemicalspolicy.org

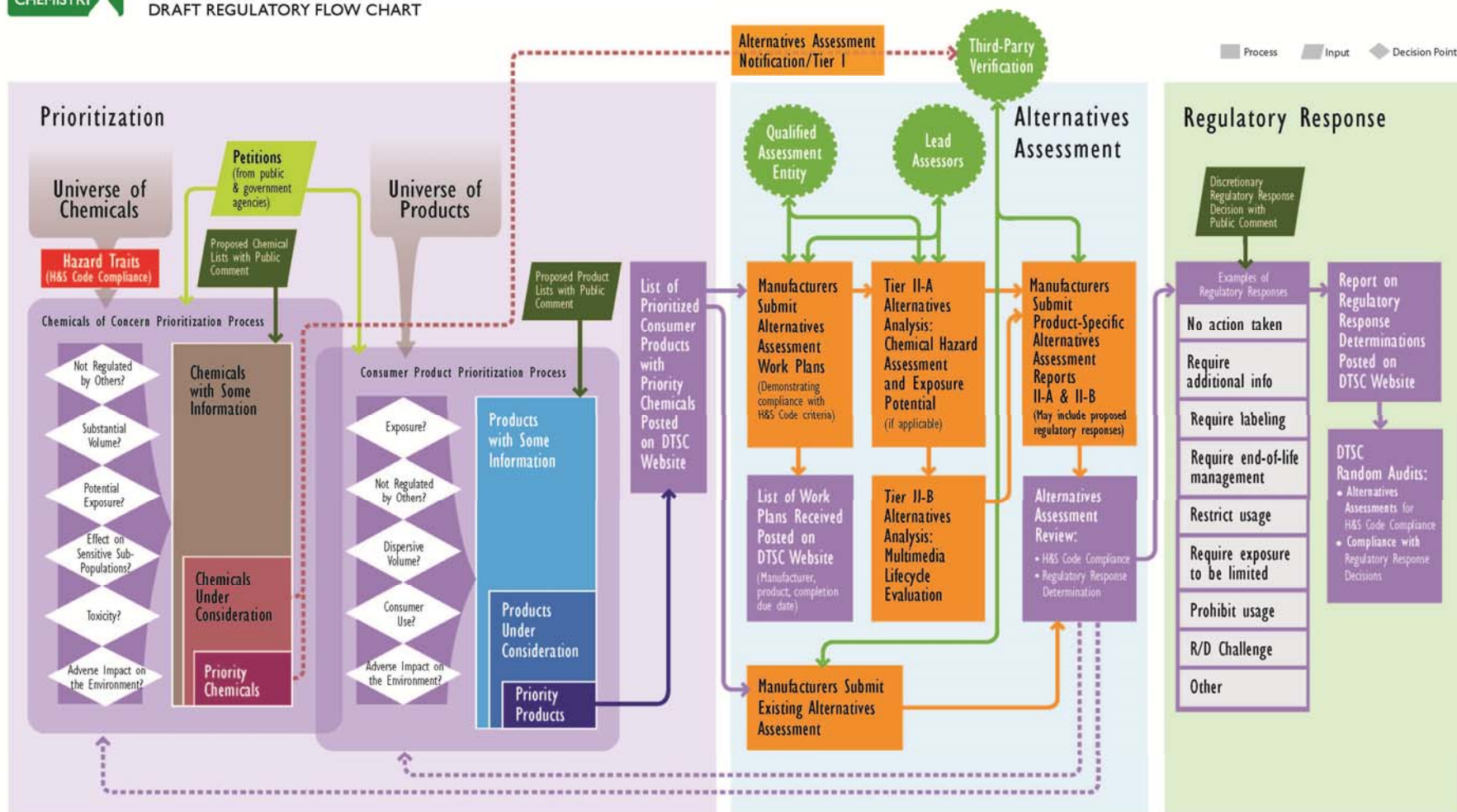
Prioritization

- Prioritization criteria:
 - Volume contained in consumer products; (what threshold for “high” priority?)
 - Potential for exposure; (e.g., is there expected, known, or anticipated release during use or at end of life?)
 - Exposure based on bio-monitoring data;
 - Potential effects on sensitive subpopulations, including infants and children;
 - Any evidence suggesting that there are “reasonable grounds for concern” regarding the potential adverse impacts of the chemical;



Regulation for Safer Consumer Products

ARTICLE 14, CHAPTER 6.5, DIVISION 20 OF THE HEALTH & SAFETY CODE
 CHAPTER 53, DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS
 DRAFT REGULATORY FLOW CHART



SEPTEMBER 14, 2010

Criteria for inclusion on Chemical Candidate List

■ Possible criteria include:

- Chemicals for which a minimum data set (e.g., SIDS data) is not available.
- Criteria established by other California regulatory programs (e.g., proposition 65) and other regulatory bodies
 - (e.g., EU REACH, Canada's CEPA);
 - Chemicals on lists established by other authoritative bodies);
 - Carcinogens;
 - Endocrine disruptors;
 - PBTs and vPvB substances;
 - Mutagens, or reproductive mutagens or toxins;

Shift burden of compliance to industry



No Data no Market



Registration per Substance



Encourage **safer products** and **better hazard communication**



Increase the competitiveness and innovation of the **EU market**



Apply the **precautionary principle** in placing products on the market

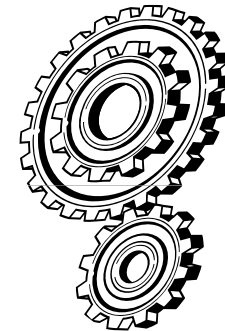


Unify EU approach to chemical regulation



Confidential Business Information

burden of proof for disclosure exemptions





Questions

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WHEN YOU NEED TO BE SURE





**Brief Introduction of
SGS US Fairfield (FF)
Chemical Lab**

WHEN YOU NEED TO BE SURE



SGS

Content



Where we located?

Who we are?

What we can do?

How we do?

How to ensure our quality?

Why SGS?



SGS IN NORTH AMERICA



SGS North America

- 84 Offices
- 100 Laboratories
- 6,300 Employees

Consumer Testing Services

SGS US Testing Company Inc

- 5 Offices
- 4 Laboratories
- 250 Employees

Where we located?



Fairfield, NJ



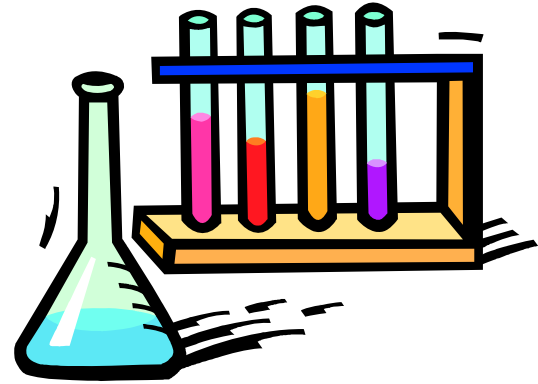
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Fairfield Lab

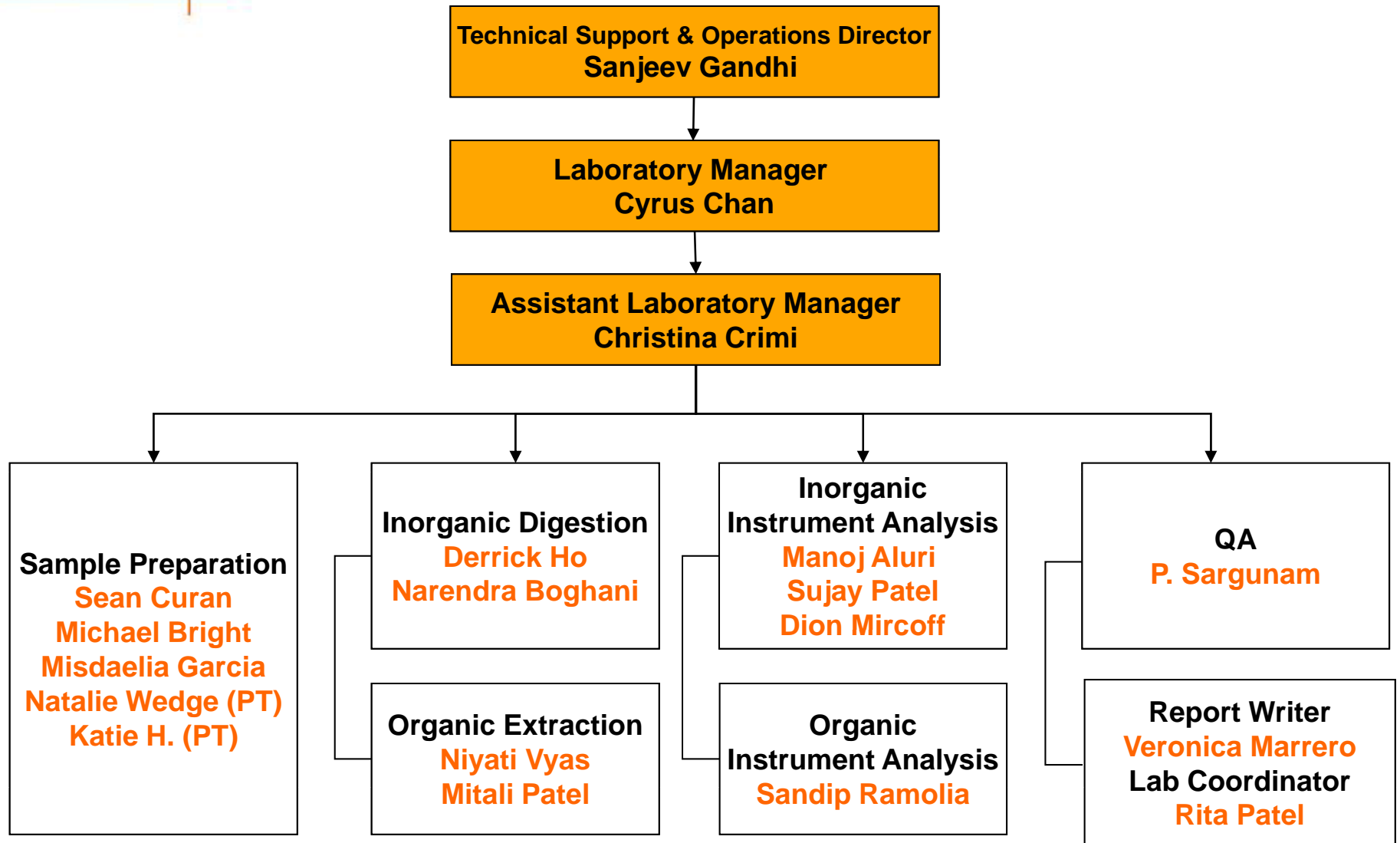


Who we are?

- Chemical Testing Center of CTS
- Serve Internal Clients/BU
- Focus on Chemical testing
- Provide technical support if needed

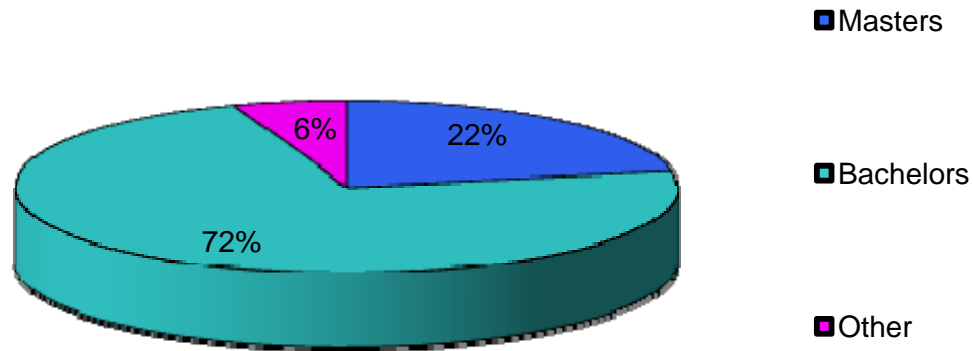


Organization Chart



Staff info

- 18 Employees, including MS, BS and other specialists
- Comprehensive training program
- Followed by on-job training program
- Technical qualification assessment for every position



What we can do?

■ Restricted substances testing according to **industry standards**, regulations and directives of USA, Canada, and EU.

- Toys and Juvenile Products
- Hardgood products
 - Housewares
 - DIY tools and building materials
- Electricals & Electronics
- Textiles
- Packaging Materials
- Others



Capability for TJP and Hardgoods Products

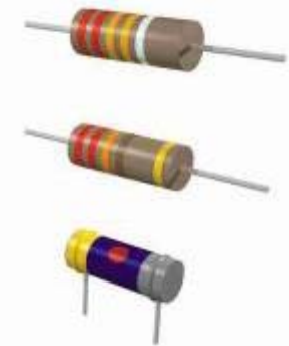
- ✓ Toys
 - **CPSIA**
 - Phthalates (DEHP, DINP, DIDP, DBP, BBP, DNOP)
 - ASTM F963, EN 71 part 3
 - CHPA
- ✓ Jewelry and other consumer products
- ✓ Heavy Metals
 - Cadmium – REACH Annex XVII
 - Nickel Release – REACH Annex XVII
 - Packaging Material – US TPCH & EU 94/62/EC
 - Plumbing fixtures (NSF 61 & EPA)
- ✓ Food Contact Material
 - US FDA: 21CFR 175-181
- ✓ Ceramic & Glassware
 - California Prop.65
 - US FDA
 -





Capability for E&E Products

- ✓ Heavy Metals & Flame Retardants
RoHS Directive 2002/95/EC
- ✓ Packing Material 94/62/EC, TPCH
- ✓ Battery Directive 2006/66/EC
- ✓ Halogens
- ✓ California Prop. 65
- ✓ Nickel Release
- ✓ PVC
- ✓ Phthalates
- ✓ Chlorinated Organic Carriers (COCs)
- ✓ Others.....





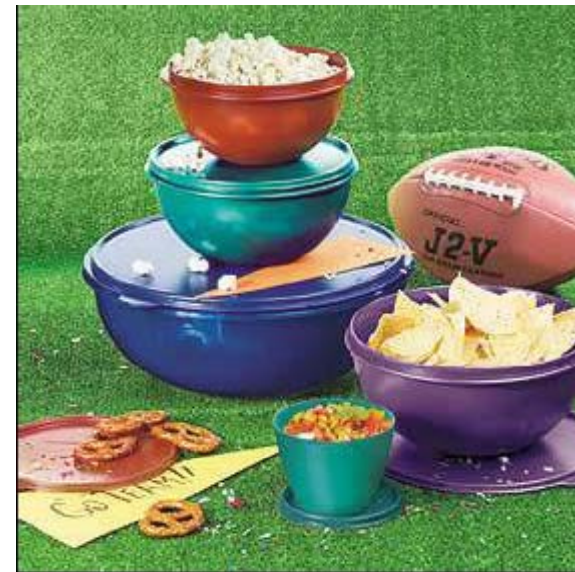
Capability for Textile Products

- ✓ Azo dyes
- ✓ COCs
- ✓ Flame Retardants – PBB/PBDE
- ✓ PVC and PU identify
- ✓ Phthalates
- ✓ Extractable Heavy Metals
- ✓ Nickel Release
- ✓ Formaldehyde



Capability for Food

- ✓ Heavy Metals
Pb, Cd, As, Hg,
- ✓ Food Packaging Material
- ✓ Others.....





How we do?

- IEC method for RoHS
- ISO, JIS, EN Methods
- CPSC SOPs
- US EPA methods
- ASTM Method
- AOAC Methods
- US FDA: 21CFR 175-181
- Several OEM methods

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▶ **Thank You**

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