



# Act 154 (H.595) Toxic Chemical Use Working Group

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# State, Federal, Global Regulations & Corporate Metrics

- GLOBALFOUNDRIES and other manufacturers within Vermont have to comply with a myriad of State, Federal and Global legislations.
- These regulations establish reporting and management requirements regarding the use or generation of a toxic substance.
- In addition, many companies have EHS metrics/commitments beyond compliance requirements:
  - Energy Conservation
  - Solid Waste Minimization
  - Green House Gas Emissions Management
  - Water Conservation

# Current Chemical & Hazardous Waste Reporting Obligations

- **SARA TIER II Report**

- Chemical State, Physical & Health Hazards, Max and Daily Amounts, Physical Storage Conditions, Container Types, Container Pressure & Temperature Conditions for Each Container
- Vermont More Restrictive Reqmts than Federal, GF reported on 188 chemicals in 2015.
  - Vermont Reporting Threshold is 100 lbs vs Federal Threshold of 10,000 lbs

- **SARA Toxics Release Inventory Report (TRI Report)**

- If SARA 313 Chemical Thresholds Are Met,
  - Must report air emissions, wastewater discharges, on-site treatments, off-site transfers, max daily on-site values for each reportable chemical
  - GF Reports on 11 Chemicals.

- **Hazardous Waste Biennial Report to the State**

- Includes State & Federally Regulated Hazardous Waste Generated, Treated & Shipped
- Applicable Hazardous Waste Source Information, Types, Disposal Site, Method, Volume & Treatment Method are Reported

- **Waste Minimization Reporting**

- **ACT 100 Plan**

- Three Year Planning Cycle for Hazardous Waste Streams > 5% of Total Waste Shipped & SARA 313 Chemicals With Usage > 10,000 lbs

- **Pollution Prevention Progress Report**

- Annual Reporting on Progress Made on Chemical Use Reduction Projects

# Current Chemical & Hazardous Waste Reporting Obligations

- **Air Emissions**

- Annual Source Emissions
- Green House Gas Emissions
- Qtrly Boiler Report & Annual QA Plan
- Boiler Compliance Testing

- **Oil Spill Preventive Containment & Countermeasures (OSPCC) Plan**

- **These Reports Typically Have Associated Fees & Require a Significant Amount of Time in Setting Up & Meeting the Compliance & Reporting Requirements**

## Global Product Compliance Requirements

- Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH)
- Restriction of Hazardous Substances (RoHS)
  - Exists in Various Geographies in World
    - India, China, Korea
    - Most Requirements Are Harmonized with Few Exceptions
      - China Has Additional Labeling Rqmts
- Conflict Minerals (Frank-Dodd)
- Prop 65 of California
- Halogen-Free Content
- Many Specific Customer Rqmts More Stringent Than Regulatory Rqmts

## Existing State, Federal & Global Chemical Regulations Based on a Framework Approach

- TSCA Modernization
- EU REACH
- California Green Chemistry (Safer Consumer Product Regulations)

# Lautenberg Chemical Safety Act

A More Effective Way  
to Regulate Chemicals

## EXISTING CHEMICALS

EPA will conduct risk-based reviews of chemicals in commerce

### Inventory Reset

- EPA maintains an inventory of chemicals, but it is difficult to tell which are used today and which are no longer in use

- LCSA requires the inventory be updated so EPA can focus on chemicals actually in use today

### Prioritization

- EPA will screen all chemicals in active use
- to identify low and high priorities for risk evaluation. Prioritization will be based on factors including hazards, uses and exposures to people and the environment, including vulnerable groups like infants, children, pregnant women and the elderly

### Low Priority Chemicals

- Chemicals can remain in use but can be reprioritized based on new information

### High Priority Chemicals

EPA will conduct a thorough risk evaluation

The first 10 high priorities must be drawn from EPA's existing TSCA Chemical Work Plan list

## NEW CHEMICALS

- EPA must review and make an affirmative safety determination before a new chemical can come to market

### Information Submitted to EPA

- Manufacturers provide information about new chemicals and new chemical uses to EPA

### Risk-Based Review

- EPA reviews information including chemical characteristics, available testing and exposure data and intended uses
- EPA can request more information if needed

### Safety Determination

- If EPA finds the chemical is not likely to present an unreasonable risk, it proceeds to market
- If the chemical presents an unreasonable risk, EPA may apply risk management measures

### Risk Evaluation

EPA Risk Evaluations will:

- Be based solely on health and environmental information
- Consider a chemical's conditions of use
- Rely on the best available studies and weight of scientific evidence
- Consider risks to vulnerable groups

LCSA makes it easier for EPA to request more testing and data from producers when needed

- 20 risk evaluations must be underway within 3.5 years

### Safety Determination

- EPA will determine if a chemical meets the law's safety standard or requires risk management

### Chemical Meets Safety Standard

Chemical may be used for its intended uses

### Chemical Needs Risk Management

- EPA's options include:
  - ▶ Labeling Requirements
  - ▶ Use Restrictions
  - ▶ Phase Outs
  - ▶ Bans

## About the Lautenberg Chemical Safety Act

- After years of negotiation and with input from many stakeholders, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) to reform the regulation of chemicals in commerce. The LCSA, enacted on June 22, 2016, protects health and the environment; supports economic growth; and promotes America's role as the world's leading innovator.

## Registration, Evaluation, Authorization of Chemicals (REACH)

- REACH is the EU's comprehensive chemical management law enacted 6/1/2007
  - All Chemicals Are Covered
    - Individual Substances or Part of Preparation
    - Substances in Articles
  - Affects Chemical Manufacturers, Chemical Importers, Downstream Users
    - Threshold of 2000 lbs/yr for Registration
    - Phase-In of 11 years for existing chemicals
  - Registration Requirements
    - Technical dossier: includes physiochemistry, toxicology, ecotoxicology data
    - Chemical safety assessment: registrations 10 TPY and higher
      - Joint registration and data sharing is encouraged, all must share vertebrate animal data
      - Includes assessments for persistent, bioaccumulative (PBT) classifications
        - PBT's must include exposure assessment & risk characterization



# Registration, Evaluation, Authorization of Chemicals (REACH)

- **Evaluation Process**

- Dossier Evaluation
  - Testing proposal evaluation
    - Authorities to approve testing protocol for vertebrate animal studies
  - Test dossier evaluation for data quality
- Substance Evaluation
  - Allows authorities to evaluate substances suspected to present a risk to health and/or environment
  - May require submission of additional data
  - Findings may dictate need for authorization or chemical restrictions

## Registration, Evaluation, Authorization of Chemicals (REACH)

- Substances of Very High Concern (SVHC)
  - Class 1&2 Carcinogens, Mutagens, or Reproductive Toxicants (**CMRs**)
  - Persistent, Bioaccumulative, and Toxic (**PBTs**)
  - Very Persistent & Very Bioaccumulative (**vPvBs**)
  - Substances of Equivalent Concern (**SEC**)
    - Chemicals meeting above criteria are placed on a “candidate” list
    - Comment period identified before being added to SVHC
      - Chemicals on SVHC subject to Authorization process
  - 15<sup>th</sup> Candidate list published to date with 169 chemicals identified as SVHC

# Registration, Evaluation, Authorization of Chemicals (REACH)

- Authorization Process

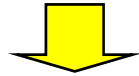
- Utilized for chemicals identified as SVHC
  - SVHC are issued a sunset date
- All use of the SVHC must be authorized by EU commission
  - Intent of authorization process is sunset the chemical & to force substitution of the SVHC
  - In summary:
    - An EU manufacturer, importer or downstream user shall not **use** or **place on the market** an SVHC on the Authorization List after its sunset date for any uses unless the EU legal entity has obtained an authorization for those uses.

- Restriction Process

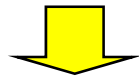
- Specific chemicals that present an unreasonable risk arising from use or manufacture
  - Restrictions may consist of the following:
    - Conditions of manufacture, use or bringing to market
    - Example: certain chemical may not be used in garments due to potential for skin contact

## California Safer Consumer Product Regulation Overview: 4-step process

**DTSC - establish list of  
Candidate Chemicals (CCs)**



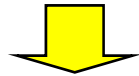
**DTSC - evaluate and prioritize  
product/CC combinations to  
develop list of “Priority  
Products”**



**Priority Products/CC**



**Alternatives Analysis (AA)**



**DTSC - Regulatory responses**

**From initial list of ~1,200 chemicals,  
based on existing authoritative lists**

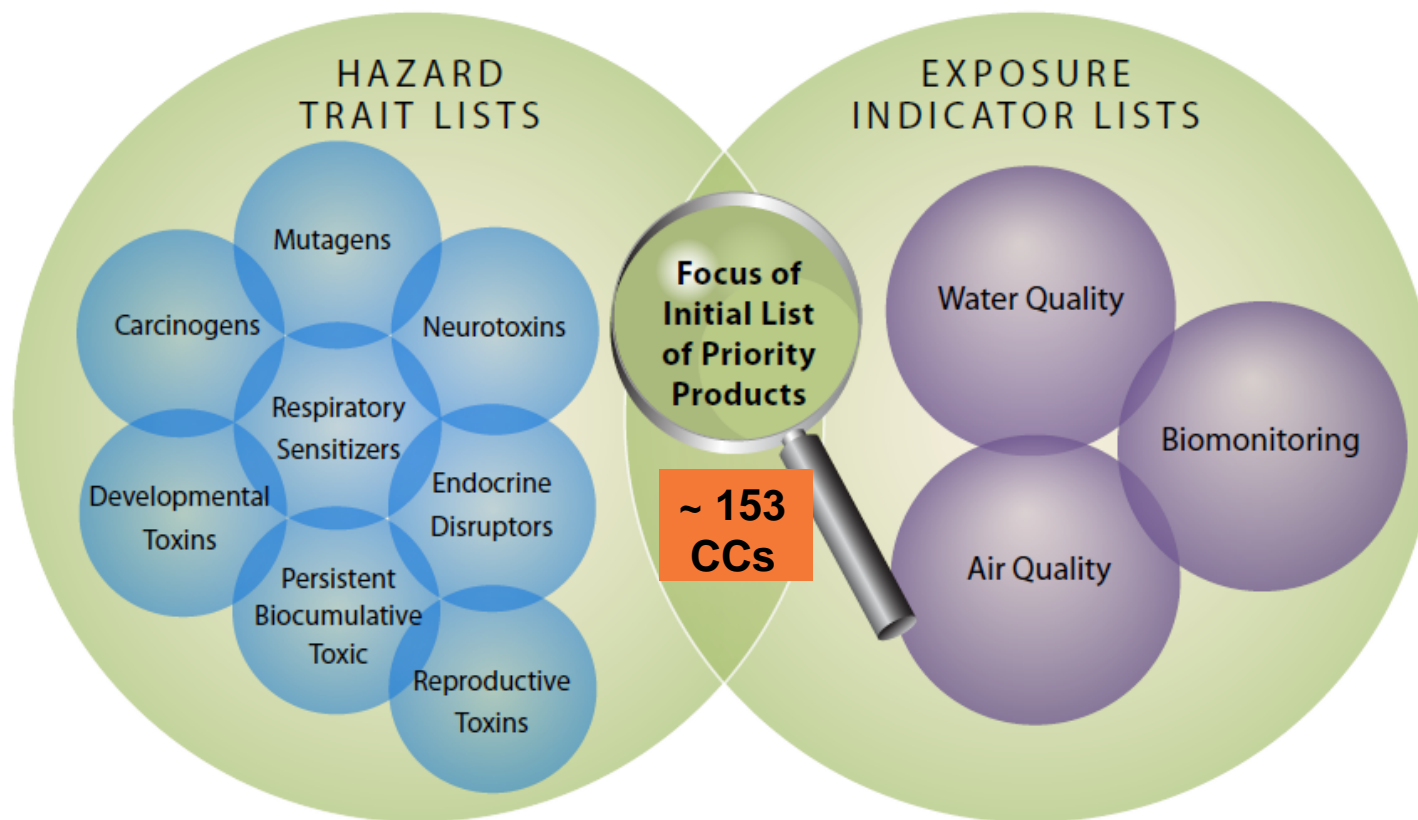
**~153 CCs evaluated (hazard traits and  
exposure concerns) for identifying  
initial Priority Products List (Draft list  
of 3 Priority Products released March  
2014)**

**Responsible entities:**

- **Notify DTSC when their product is  
listed as a Priority Product**
- **Conduct AA**

**DTSC identify and imposes regulatory  
responses designed to protect public  
health and/or the environment**

# Initial Candidate Chemical List



## Product-Chemical Identification & Prioritization Factors

- Key Prioritization Principles - Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:
  - There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product;

and

  - There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts

## Alternatives Analysis (AA)

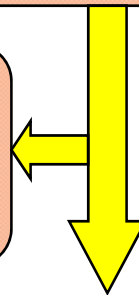
- An evaluation and comparison of a Priority Product and one or more alternatives to the product
- Before finalizing the initial Priority Products list, DTSC shall make available guidance materials to assist persons in performing AAs
- An AA to be conducted in two stages

### Preliminary AA Report

**Submitted no later than 180 days after date a product is listed as Priority Product**

### Abridged AA Report

**No functionally acceptable and technically feasible alternative available**



### Final AA Report

**Submitted no later than 12 months after date DTSC issues notice of compliance for Preliminary AA Report**

# Regulatory Responses

**Supplemental information**

**DTSC may require information supplemental to AA report**

**Product information for consumers**

**Regulations specify types of information that must be provided and mechanism used to provide information**

**Use restrictions**

**Restrictions on use of COCs or replacement CC in selected alternative, or COC in PP, or restrictions on product**

**Product sales prohibition**

**Cease placing product into stream of commerce in CA**

**Engineering safety measures or administrative controls**

**Engineer safety measures that integrally contain or control access to, and/or implement administrative control that limit exposure**

**End-of-life management requirements**

**Establish and maintain end-of-life management program for product**

**Advancement of green chemistry and green engineering**

**When no acceptable/feasible alternative available – initiate R&D project or fund green chemistry/engineering challenge grant pertinent to PP**



## Final Thoughts

- Must study all regulations at the State, Federal and Global level that are currently addressing the use or generation of toxic substances or hazardous waste
- Must understand what those regulations cover and whether there is currently any interplay between different regulations
- Who is the current regulated community
- What are the current reporting requirements and deliverables from these regulations
- Where does the information reside and is it readily accessible and how is it utilized
- Any gaps that exist that are not addressed relevant to the ability of the State to improve the human health and the environment
- How are other geographies creating framework of Chemical Management regulations
  - Recommend a deeper dive into EU's REACH and TSCA reform
  - Avoid duplication, focus on harmonized requirements

## Final Thoughts....cont

- Avoid redundancy or inconsistency with existing federal & international regulations
  - Thresholds
  - Material Content
  - Labeling
- Inconsistencies across jurisdictions represent a serious concern for compliance, market access & global flow of commerce
  - Most large companies have a worldwide supply chain & ships products to many countries
- Base regulations on sound scientific evidence
  - Key Factors: Fate & Transport, Exposure, Toxicity
- Adequate timelines needed for bans or restrictions of chemicals
  - Assessment & selection of an alternate chemical can be a complex & time consuming process that requires:
    - Obtaining information for various components in the product
    - Identification of possible alternate chemicals for evaluation
      - Requires regulatory, safety, technical & economic feasibility analysis
      - There is no “one-size-fits-all” process for replacement of a material
  - Full qualification of alternate material

# Thank you



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