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Chemical Law in the US and EU: How to Manage Increasingly Stringent Requirements

September 23, 2014

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Agenda

- Chemical Law Issues Affecting Products and How Companies Have Responded
- Thinking About Integrated Corporate Management and Product Stewardship
- Questions & Answers

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Our Panel

- **Michael Walls**, Vice President of Regulatory and Technical Affairs, American Chemistry Council (Washington)
- **Anthony Samson**, Policy Advocate: Environmental Regulation, Housing and Land Use, California Chamber of Commerce (Sacramento)
- **Lucas Bergkamp**, Partner, Hunton & Williams (Brussels)
- **Dan Uyesato**, Partner, Hunton & Williams (Raleigh)
- **Malcolm Weiss**, Partner, Hunton & Williams (Los Angeles)

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Chemical Policy Developments Affecting Products: Impacts and Implications

Michael P. Walls
Vice President, Regulatory & Technical Affairs

American® Chemistry Council

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Trends in Global Chemical Regulation

- Rise of “marketplace regulation”
- Democratization of chemical data
- Increasing rate of de-harmonization
- Controversy in fundamental science
- Decline of basic assessment processes

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Impact of Trends

- Trends reflect perceptions about the effectiveness of chemical regulation
- Trends drive:
  - Unwarranted chemical deselection
  - Increase in divergent regulatory requirements
  - Inconsistent policy means & objectives
  - Relief sought outside traditional arenas

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Trans-Atlantic Trade and Investment Partnership (TTIP)

- Goal: Comprehensive agreement
- 2013 two-way chemical trade = $57 billion
- Eliminating remaining import duties would save $1.5 billion/year
- Potential savings from enhanced US-EU regulatory cooperation on chemicals are even greater

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Opportunities for US-EU Regulatory Cooperation

- Address regulatory divergence and seek efficiencies within/between systems
- **Not** about harmonizing REACH and TSCA
  - Maintain high levels protection
- Explore opportunities for burden sharing
- Enhance scientific cooperation and procedural coherence
- Improve transparency

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Implications

- Increased pressure on manufacturers and suppliers for ingredient disclosure
- Mixed experience in challenging regulatory decisions on technical/science issues
- Mixed experience in value of industry or voluntary measures
- Continued public distrust of regulatory systems, manufacturers and users

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The EU REACH Regulation and Product-Specific Chemical Regulations

Prof. Lucas Bergkamp
Partner, Hunton & Williams LLP

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Why Was REACH Adopted?

- Commissioner Wallström: "We are unwittingly testing chemicals on both living humans and animals." This is "an **unacceptable knowledge gap**"
  - "No data, no market"
- Europe wants a "**toxic-free**" living environment
  - **Wallström's blood test**: 28 of 77 chemicals analyzed were present, including PBDEs (Poly Brominated Diphenyl Ethers), PCBs (Poly Chlorinated Biphenyls) and OCPs (Organo Chlorine Pesticides)
- Heavily lobbied, final was better than initial proposal

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REACH's Multiple Objectives

- **High level of protection** of human health and the environment
- **Promote alternative methods** for assessment of hazards of substances
- **Create internal market**: free circulation of substances on the internal market
- **Enhance competitiveness** and **innovation**
- **Industry responsibility to ensure that substances are safe** and used safely
- **Implement precautionary principle**

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REACH's Design

- **REACH is a series of regulations**: registration, evaluation, authorization, restriction, supply chain information, SDSs, customer and consumer information, etc.
- REACH's multiple regimes jointly constitute a **comprehensive chemicals regulatory structure** that attempts to capture **all adverse effects** of all chemicals **over their entire life cycle** and in **all uses**
- REACH employs **several instruments,** from **information** to **command and control regulation**
- REACH applies, not in lieu of, but **in addition to product-specific chemical regulations**

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REACH's Characteristics

- **REACH is tremendously complex**
  - Each regime raises issues, and details of the relations between the constituent parts are often unclear
- **REACH can be an enormous bureaucracy**
  - **Vast amounts** of data and information to be filed with ECHA, and **updates** are required
  - Tests may be required **even if deemed "useless"**
- **REACH results in inefficiencies**
  - Role of authorization, given restrictions regime
  - Regulations other than REACH may be better suited to address issue

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REACH's Various Regimes and Issues Arising Under It

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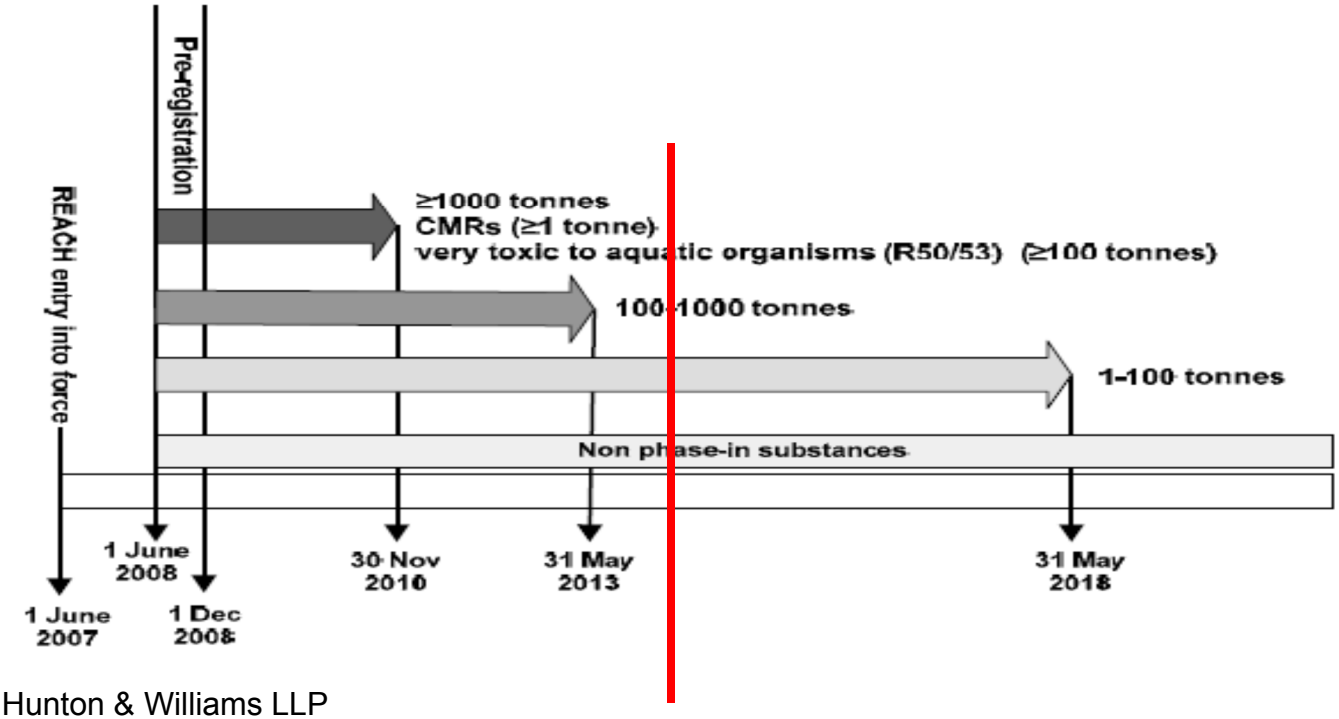
Registration and Evaluation

- **Registration**
  - Staggered registration deadlines
  - Information requirements increase with tonnage band



Cost estimate (2007):

≥1000: $2.6 million

100-1000: $1.2 million

10-100: $520,000

1-10: $105,000

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Registration and Evaluation

- ECHA received nearly **40,000 registrations** for **7,877 substances** thus far
- ECHA expects to receive up to **70,000** additional registration dossiers by **May 31, 2018**
- **Quality of dossiers submitted is not consistently high**
  - ECHA is going through some of them and issuing draft decisions as it goes along

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Registration and Evaluation

- **Evaluation**
  - **Compliance check**: ECHA must assess compliance of at least **5%** of all registration dossiers
  - **Substance evaluation**: ECHA may also request any additional information, including non-standardized tests, if it has a "concern"
  - By 2018, ECHA expects to conduct between **150 and 350 compliance checks per year** and between **35 and 45 substance evaluations per year**

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Dossier Evaluation

- ECHA interprets data and testing requirements in some cases "**by the letter**," in other cases, "**creatively**," and even **departs from its own guidelines**
  - Above 1,000 tons per year, ECHA requires a **developmental study in a second species** as a **standard requirement**, despite clear wording to the contrary in REACH and ECHA guidelines
  - ECHA significantly **narrowed the concept of "intermediate"** in the second version of its guidelines on intermediates, excluding, for example, catalysts

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Substances in Articles

- Suppliers of articles must provide safety information to their **customers** and, upon request, to **consumers**, if a substance of very high concern (**SVHC**) on the Candidate List is present in an article above 0.1%, whether **intentionally added or not**
- Currently, **155 SVHCs** on Candidate List
  - Candidate List is updated twice per year
- This is a **supply chain management issue**
  - Companies tend to adopt a **risk-based approach**, using testing only as a last resort

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Command and Control

RESTRICTION

- Generally binding, for **risk not adequately controlled**
- Open-ended, but must be **tailored to the risk** (e.g., labeling requirement)
- About **60 substances restricted** thus far

AUTHORIZATION

- **Hazard-based approach,** intended to **phase out SVHCs**
- **All uses** are subject to prior authorization, with limited exceptions
- Currently, **22 substances** subject to authorization (updated once per year)
- **1 authorization** granted thus far

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Restriction, Authorization or Other?

- Should **all SVHCs** go on **Candidate List** and then on Annex XIV for **authorization**?
  - ENGOs: Yes, and Yes
  - Industry: Depends
  - **Commission: Yes, and No**
- REACH proceeds "**one substance at a time**"
  - Creates problems of **consistency** and **unintended substitution effects**
  - Commission has developed **Risk Management Option (RMO) Analysis**

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Restriction, Authorization or Other?

- Could the **least onerous, most appropriate risk management measure** be taken under another regime, instead of REACH?
  - If the sole risk is **occupational**, an occupational exposure limit (EOL) may be the preferred option
  - If the sole risk is **product-specific**, a regulatory measure under a product specific regime may be the preferred option

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Product-Specific Chemical Regulations

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Product-Specific Chemical Regulations

- REACH **replaced** a series of chemical directives and regulations
- **Pre-existing product-specific chemical regulations** (such as RoHS) were not amended, causing issues of coordination
- The idea was that, going forward, substances would be regulated pursuant to REACH
- **REACH has not reduced the EU's legislature appetite for new product-specific chemical laws, however**

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Product-Specific Chemical Regulations

- **Product-specific chemical regulations are in place for electronics, toys, cosmetics, biocides, pesticides, etc.**
  - **Overlaps** are not excluded, resulting in **increased cost** and **complexity** for industry
  - For example, DEHP will likely soon be covered by RoHS, and, if so, companies might be **required to request both an** authorization under REACH and an **exemption under RoHS** for the same use of DEHP

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Product-Specific Chemical Regulations

- Increasingly, the EU prefers **regulations** over directives, because the former are **directly applicable** in all Member States
  - If Member States do not issue their own regulations, this should result in **increased harmonization** between the 28 Member States
- These regulations increasingly include **hazard-based** elements (or proxies for risk or exposure)
  - For example, **CMRs are banned in cosmetics and biocides**, subject to limited exceptions

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Conclusions

- **Smart REACH compliance often requires negotiations with ECHA**
- REACH does **not** follow a logical **risk assessment, cost/benefit analysis, and policy analysis model**, and pays little attention to risk/risk trade-offs and unintended substitution
  - EU chemical regulation proceeds both in the context of REACH and outside of it, with little predictability
- This means that companies need to be engaged, provide **input in regulatory processes**, and **monitor business impact**

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Thank you for your attention!

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California's Proposition 65

(aka Safe Drinking Water and Toxic Enforcement Act of 1986)

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Overview

- Aggressive consumer right to know law
- Consumer products, work place and environmental exposures
- 800+ listed chemicals (cancer and reproductive harm)
- Stiff penalties, prosecutor and citizen enforcers
- Warning or reformulation

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2013 Enforcement Statistics

- 352 settlements
- Total payments $17,400,000+
- Plaintiff attorney fees $12,730,000+ (73%)
- Penalties $2,680,000+ (15%)
- Payments in-lieu-of penalty $1,998,000+
- Defense attorney fees

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Proposition 65 Warning Regulation Proposals

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Policy Advocate: Environmental Regulation, Housing and Land Use,
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Proposition 65 Warning Regulation Proposals

Original Proposal	Anticipated Revised Proposal
Eliminates “Safe Harbor” warning concept	Reintroduces “Safe Harbor” warning concept
Website: Subject to private right of action / contained mandatory reporting requirements	Website: Not subject to private right of action / eliminates mandatory reporting requirements but allows OEHHA to request information from businesses using a “data call-in” format
	
“will expose”	“can expose”
Grandfathered warning systems resulting from court-approved settlements for businesses that were a party to the lawsuit only	Businesses that were not a party to the lawsuit may request OEHHA’s permission to adopt court-approved warning systems
Warnings must specify if product/facility contains one of 12 specified chemicals	No change

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US Federal Chemical Law and Possible TSCA Reform

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Sources of Federal Chemical Product Regulation

- Toxic Substances Control Act (TSCA)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Occupational Safety and Health Act (OSHA)
  - Hazard Communication Standard
- Federal Hazardous Substances Act (FHSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Food Drug and Cosmetics Act (FFDCA)
  - Indirect Food Additives
- Clean Air Act
  - Regulation of fuels and fuel additives
  - Regulation of Ozone Depleting Substances (Montreal Protocol)

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Toxic Substances Control Act (TSCA)

- TSCA regulates chemicals by generally prohibiting the manufacture, import or distribution of any chemical substance not on the TSCA Inventory or the "significant" new use of certain previously inventoried chemicals
  - Exclusions: mixtures, pesticides, food, drugs, food additives, devices, cosmetics, articles, radioactive materials, tobacco and tobacco products
  - Exemptions: R & D Chemicals, certain polymers (annual reporting), export only chemicals
  - Exemptions for which Submissions required: Low Volume (LVE), Low release/exposure (LoREX) and Test Marketing (TME)

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TSCA Inventory

- TSCA Inventory (Public & Confidential)
  - List of all chemical substances that can legally be manufactured or imported for distribution in the US
    - Currently about 84,000 chemicals
- Inventory status defines whether new or existing
  - Existing – on inventory
  - New – not on inventory; Section 5 requires company to submit Premanufacture Notice (PMN) to US EPA to get chemical on Inventory

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Safety Standard – New & Existing Chemicals

- TSCA Threshold For the Regulation of the Manufacture, Processing Distribution in Commerce, Use or Disposal of A Chemical Under TSCA, EPA Must Determine that It Presents an "Unreasonable Risk of Injury to Health or the environment"
- "Unreasonable Risk" Determination Requires Consideration of Both Risks and Benefits
- EPA Must Also Regulate Only to the Extent Necessary to Adequately Protect Against an Identified Risk and Must Take the "Least Burdensome" Regulatory Approach

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New Chemicals – Premanufacture Notice

- EPA PMN Review to determine whether chemical:
  - "may present an unreasonable risk of injury to health or the environment or"
  - "will be produced in substantial quantities, and … enter the environment insubstantial quantities or there …may be significant or substantial human exposure."
- If EPA has made an adverse determination, then it will take action to prevent the PMN from being added to the Inventory
  - If restrictions may make PMN approvable, it may approve PMN subject to Consent Order
- If EPA determines that the information in the PMN is insufficient to permit a reasoned evaluation, it will require more data
- If none of the above, EPA will take no action within prescribed 90 days, and upon submission of a Notice of Commencement, the chemical will be added to the Inventory

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Significant New Use Rule

- Rule promulgated to cover activities not identified in PMN that may result in increased exposures or releases and that may present an unreasonable risk of injury to health of the environment
- Significant New Use Notice (SNUN) required if use changes
- Historically, SNUR initiated by 5(e) Consent Order with submitter to extend Consent Order terms to other parties
  - Trend now to skip Consent Order

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Section 4 – Testing for Existing Chemicals

- TSCA Assumes "Existing Chemical" is safe unless EPA determines that It may present an "Unreasonable Risk of Injury to Health or the Environment" or it is produced in very large volumes with potential for either substantial quantities to be relased into the environment or significant human exposure
- EPA can require manufacturers, importers and processors of a chemical to conduct testing on its human health and environmental effects, generally pursuant to Consent Orders

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Confidential Business Information (CBI)

- Section 14 of TSCA allows companies to assert CBI claims for certain information submitted to US EPA, including process information, impurities and chemical identity.
  - Balance IP rights of submitters vs. public right to know
  - Only 5% of PMNs submitted to date have been completely nonconfidential
  - Increased pressure from public to reduce right of submitters to claim CBI, especially chemical identity
    - 8/21/14 Earth justice petition under §4 of APA for EPA rulemaking to limit duration of CBI status to 5 years unless prior to expiration company demonstrates the information still qualifies.

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Information Requirements Under TSCA

- Section 8(a) Preliminary Assessment Information Rule (PAIR) – Allows US EPA to collect information by rulemaking
- Section 8(a) Inventory Update Rule (IUR)/Chemical Data Reporting Rule
  - Production, Use and Exposure Information on Substances Meeting Threshold Every Five (5) years
- Section 8(c) Allegations of Adverse Effects
- Section 8(d) Health and Safety Studies
  - Chemicals identified by Rulemaking
- Section 8(e) Substantial Risk Information
  - Must be immediately reported to US EPA

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Risk Management Authority under Section 6

- US EPA has authority under Section 6 to impose various risk management options
  - Labeling Requirements
  - Recordkeeping Requirements
  - Use Restrictions
  - Bans
- Only Five Existing Chemicals Restricted Under Section 6, and for Asbesos, Most Restrictions Were Vacated By the Fifth Circuit Court of Appeals Because the Court found EPA Rule not based on substantial evidence (i.e., insufficient cost-benefit analyses)

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Pre-emption of State and Local Law

- TSCA does not restrict right of states or local governments to regulate chemical risks governed by TSCA except where
  - EPA has issued a rule requiring testing of that chemical and
  - EPA has issued a rule or order regulating a chemical (other than its disposal), unless they are identical to EPA's, carry out another Federal law or ban the use of that chemical (other than its use in manufacturing or processing other chemicals)
- EPA may allow an otherwise preempted law or regulation if it is consistent with EPA TSCA actions, affords a higher degree of protection and does not unduly burden interstate commerce.

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Concerns Driving TSCA Reform

- Regulatory Burden on EPA to Require Manufacturers/Processors to Conduct Testing on Existing Chemicals Has Prevented EPA from Conducting Adequate Safety Assessments on Vast Majority of Chemicals in Commerce
- TSCA's Safety Standard is Too Stringent
- TSCA's CBI Provisions Impede the Public's Ability to Take Appropriate Actions Respecting that Chemical
- Above Concerns Drive State & Local Government to Regulate, Increasing Compliance Cost With No Demonstrable Regulatory Benefit

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Four Major Issues of TSCA Reform

- Increased Obligations to Provide EPA with Hazard, Use and Exposure Information for both New and Existing Chemicals as a Condition of Market Access
- Make EPA Safety Standard More Stringent
  - Instead of Threshold for Regulation, a Threshold for a Chemical to Be in Commerce
  - Shift Burden from EPA to Regulated Community and Eliminate Consideration of Non-risk Factors (e.g., no cost-benefit analysis)
- Restrict TSCA CBI Protections - Chemical Identity, Studies Generating Required Data Not Covered
  - Trade Secret/Data Compensation
- Extent of Preemption

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Recent TSCA Reform Efforts

- In May 2013, Senators Frank Lautenberg (D) & David Vitter (R) introduced bipartisan TSCA reform bill, the Chemical Safety Improvement Act, S. 1009 (CSIA)
  - Supported by industry trade associations and public advocacy groups
  - Increased EPA's authority to require testing of and otherwise regulate chemicals, but addressed needs of regulated community, e.g., provided for reasonable timetables for implementation, required EPA to prioritize chemicals, provided opportunity for exemptions, more reasonable CBI provisions and provided for some preemption of state and local laws regulating chemicals
  - Senator Lautenberg died shortly after the bill's introduction; Senator Boxer shortly thereafter raised serious reservations about bill, especially its preemption provisions.

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Recent TSCA Reform Efforts (cont.)

- In early 2014, Rep. John Shimkus (R), Chairman of the House Subcommittee on Environment and the Economy, held several hearings and introduced various discussion drafts of TSCA reform legislation (Chemicals in Commerce Act) similar to CSIA
  - House Democrats' counterproposal showed that the parties were far apart, and the counterproposal was criticized by industry groups and others; committee vote originally scheduled for late June 2014 postponed indefinitely

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Recent TSCA Reform Efforts (cont.)

- In Spring/Summer 2014, behind the scenes negotiations were conducted between Senators Vitter and Tom Udall (D), Senate Superfund, Toxics & Environmental Health subcommittee chairman over CSIA; Senator Vitter generated a working draft dated 7/31/14 (which was not made public) reflecting those negotiations, which was submitted to Committee Chairman Boxer.
  - On September 18, 2014, Senator Boxer announced her counterproposal to the 7/31/14 CSIA working draft hammered out by Senators Vitter and Udall, releasing her markup of that previously unreleased draft, stating that the “Vitter draft” had “serious flaws”.

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Recent TSCA Reform Efforts (cont.)

- Most strenuous objection was to any preemption of state or local laws, although also objected to EPA timetables (not aggressive enough), EPA ability to exempt chemicals from regulations, that safety standard was not stringent enough, absence of funding mechanism, and failure to require EPA to take expedited action on PBT chemicals or on asbestos
- After Senator Boxer's announcement, Senator Vitter indicated that he would start over next year with the original version of CSIA (S. 1009).
- TSCA Reform off the table for the rest of 2014

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Thank you for your attention!

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Emerging Issues: Combined Effects, Endocrine Disrupters and Nanotech

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Why Are These Issues Emerging?

- **ENGOs** and other organizations express concerns
- **Mass media** report regularly on new issues and general public lacks ability to evaluate reports and scientific studies (e.g., association versus causation)
  - **Vicious circle**: scientific publication → media report → public concern → regulators get concerned → regulation, more science, etc.

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Why Are These Issues Emerging?

- EU Treaty requires that environmental and health and safety policies aim at "**high level of protection**"
- EU Treaty specifies policy principles
  - Sustainable development, prevention, polluter pays
  - "**The precautionary principle**"
    - REACH Regulation is based on it
    - **Hazard-based regulation** is on the rise

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EU Environmental Policy

- EU's 2020 environmental program is aimed at developing a strategy for a "**non-toxic environment**" by 2018 with the following priorities:
  - Appropriate regulatory approaches to address **combined effects (synergystic effects)** of chemicals
  - Minimization of exposure to **endocrine disrupting chemicals**
  - Safety of manufactured **nano-materials** and materials with similar properties

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EU Environmental Policy

- This strategy should build on "**horizontal measures** to be undertaken by 2015"
  - Risk assessment
    - Precautionary?
    - Qualitative?
    - WoE?
  - Restrictions and other regulations?

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Combined Effects

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Combined Effects

- Combined effects of chemicals refer to exposure to multiple chemicals below their respective safety thresholds, which, in the **aggregate**, could be harmful
- Current regulatory approaches, including REACH, are based on the **evaluation of individual chemicals**

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Combined Effects

- The Commission issued a roadmap to address combined effects in 2012
  - The Commission noted that there may be a **combined effect of chemicals with common modes of action**, but not a combined effect of chemicals with different modes of action
  - At this stage, the Commission is focusing on **filling the data gaps**, in particular on the assessment of exposure and modes of action, rather than imposing new requirements on companies
- The Commission will release an **interim report in 2015**

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Endocrine Disrupters

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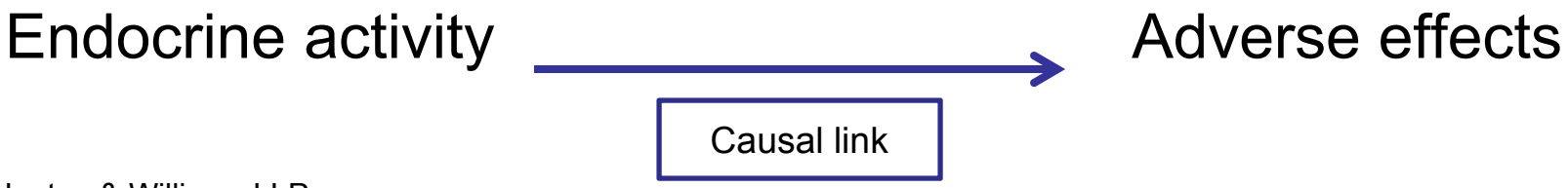
Endocrine Disrupters

- **Not defined** in any EU regulation, nor any legal or regulatory criteria as of yet
- Definition of **WHO/IPCS** is generally accepted:
  - *"An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and **consequently causes adverse health effects** in an intact organism, or its progeny, or sub)populations."*



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Endocrine Disrupters

- 2006: REACH Regulation defines "**substances of very concern**" to include endocrine disrupters, which thus may be **phased out** through authorization regime
  - There are currently **four endocrine disrupters** on the **Candidate List** and four more are expected to be included by the end of the year

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Endocrine Disrupters

- 2009 Cosmetic Regulation requires **review of risks** of endocrine disrupters in **cosmetics** by 2015
- 2009 Plant Protection Product Regulation **bans** endocrine disrupters from **plant protection products**
- 2012 Biocide Regulation **bans** endocrine disrupters from **biocidal products**
- 2014: European Parliament **proposes to ban endocrine disrupters from medical devices and packaging**

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Endocrine Disrupters

- Commission was required to issue criteria by December 2013, but is planning only to conduct an **impact assessment** by the end of this year
  - Sweden is challenging this delay before the Court of Justice
  - Impact assessment will likely focus on the proposals set out in the Commission's roadmap (see next slide)

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Endocrine Disrupters

- The Commission recently released a **roadmap** including **regulatory options**:
  - **Identification of endocrine disrupters**: based on WHO/IPCS definition, which could be supplemented with
    - (i) classification based on the **strength of the scientific evidence** of meeting the definition; and/or
    - (ii) **level of potency** (low potency endocrine disrupters would be excluded from regulation)
  - **Regulation of endocrine disrupters: hazard-based regulation**, which might be supplemented with (i) risk assessment or (ii) socio-economic considerations

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Nanotechnology

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Nanomaterials

- December 2008: CARACAL states that nanomaterials can be treated as **phase-in substances** under REACH
- October 2011: Non-binding Commission **definition**:
  - "a *natural, incidental or manufactured* material containing particles, in an **unbound** state or as an **aggregate** or as an **agglomerate** and where, for **50% or more of the particles in the number-size distribution**, one or more external dimensions is in the size range **1 nm-100 nm**. […]"

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Nanomaterials

- October 2012: Second Commission regulatory review:
  - "Nanomaterials are similar to **normal chemicals/substances** in that some may be toxic and some may not."
  - "Current **risk assessment methods are applicable**, even if work on particular aspects of risk assessment is still required."

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Nanomaterials

- Some Member States are pushing the European Commission for **faster and more ambitious actions** and, in the meantime, they are moving ahead with their own regulatory programs:
  - **National nanomaterials registries** have been adopted by Belgium, Denmark, France and Norway
  - Sweden is considering registry
- EU legislation contemplates possible further measures (see next slide)

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Nanomaterials

- **Commission to review and consider further measures**:
  - RoHS-2 (2011) and WEEE-2 (2012)
- **Safety assessment requirement**:
  - Cosmetic Regulation (2009) and Biocide Regulation (2012)
- **Labeling requirement**:
  - Cosmetic Regulation (2009), Food Labeling Regulation (2011) and Biocide Regulation (2012)

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Nanomaterials

- **Notification requirement:**
  - Cosmetic Regulation (2009)
- **Authorization**:
  - Plastic Food Contact Material Regulation (2011)
- **Upcoming for medical devices**:
  - Safety assessment and labeling requirements under the upcoming Medical Devices Regulation

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Nanomaterials

- The Commission is also considering:
  - **Amendments to REACH annexes**
  - **EU-wide nano-materials registry**
- Public consultations on these two proposals were recently closed and the Commission will soon make a decision, and possibly submit a legislative proposal to the European Parliament
- The Commission is also expected to **review its non-binding definition** and the definition of nano-materials under the Cosmetic Regulation in the near future

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Conclusions

- Combined effects, endocrine disrupters, and nanomaterials are very much **on the radar screen** of policy makers
- The two main factors deciding their fate are:
  - **Science**, including the extent to which it will be designed to reduce false negatives over false positives
  - **Legislation**, and the **regulatory framework** for risk assessment and risk management

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Thank you for your attention!

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California's Green Chemistry
(Safer Consumer Products)

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California's Green Chemistry (Safer Consumer Products)

- Background/Goals
  - What is Green Chemistry?
  - SCP goals
  - Initial failed efforts
  - Reaching the middle ground

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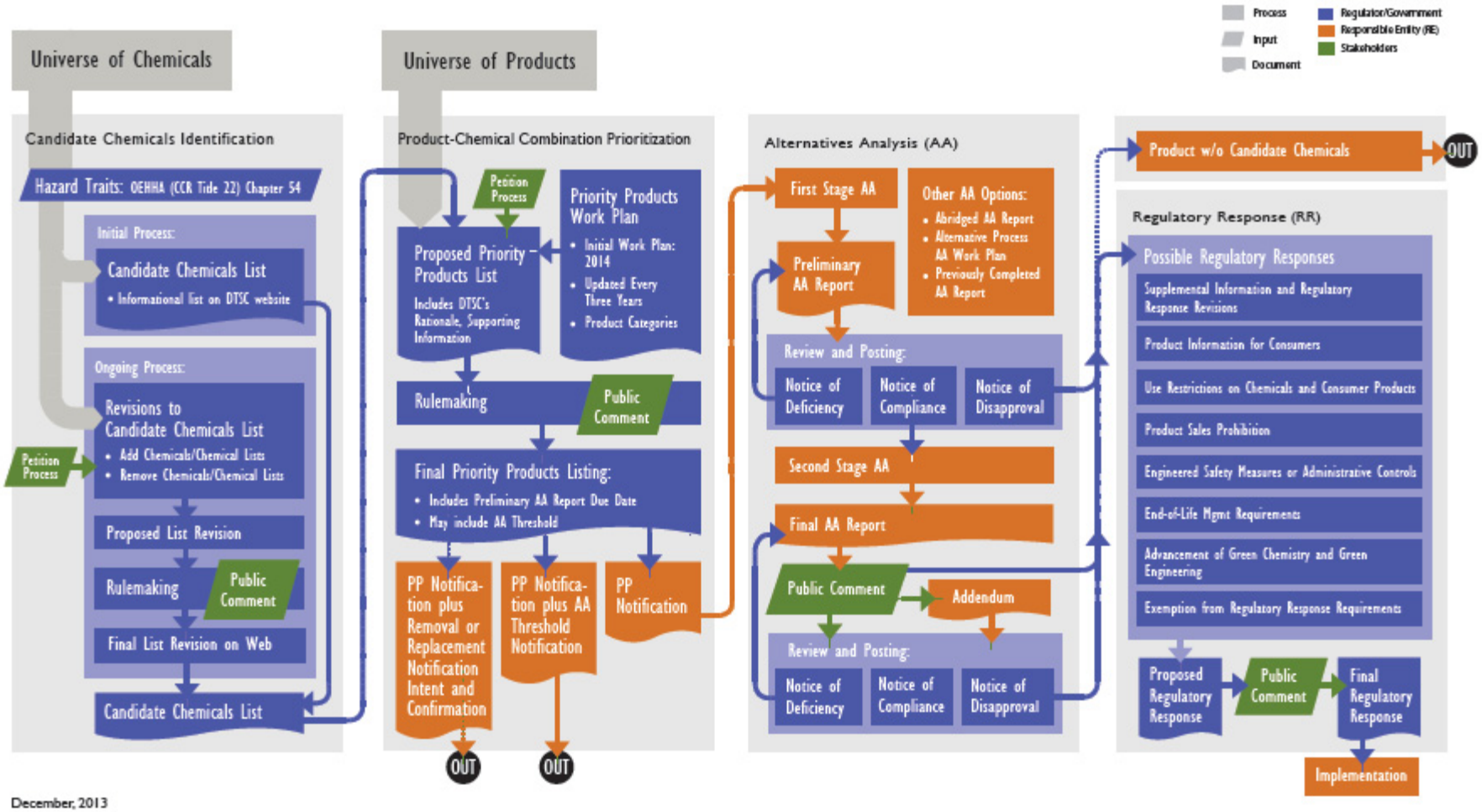
Current Status

- Regulations effective Oct. 1, 2013
- ~1200 Candidate Chemicals (CC)
- Priority Products (PP)
- Alternatives Analyses (AA)
- Regulatory Responses (RR)

Regulations for Safer Consumer Products

ARTICLE 14, CHAPTER 6.5, DIVISION 20 OF THE HEALTH & SAFETY CODE
CHAPTER 55, DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS (CCR)
DRAFT REGULATORY FLOW CHART



December, 2013

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Priority Products and Candidate Chemicals

- Spray polyurethane foam systems containing unreacted diisocyanates
- Children's foam-padded sleeping products with TDCPP (tris(1,3-dichloro-2-propyl) phosphate)
- Paint stripper with methylene chloride

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Priority Product Work Plan

- Identifies product categories from which PPs will be selected
- Public comments (9/25 and 9/29)
- Identify product/chemical combinations for additional PPs
  - Hazard trait and endpoint, route of exposure, chemical prioritization, evidence of exposure, sensitive subpopulations, functional use, existing research/nomination process

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Priority Product Work Plan

- Product Categories of Interest
  1. Beauty, Personal Care and Hygiene Products
  2. Building Products and Household/Office Furniture and Furnishings
  3. Cleaning Products
  4. Clothing
  5. Fishing and Angling Equipment
  6. Office Machinery (consumables)

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Implications and Conclusions

- SCP has the potential to significantly impact products you make (manufacturer) and/or sell (retailer)
- Good deal of uncertainty going forward
- Some impacts or liability scenarios are reasonably foreseeable, many are not
- Aggressively participate if products you make or sell are identified in the PP Work Plan

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Compliance Management, Supply Chain Management, Including Contracts and Audits

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Chemicals Regulation – Compliance Management Challenges

- Depends on Type of Regulatory Regime
  - TSCA & Other Inventory-Based Systems
    - Vast majority of compliance burden on chemical importers/mfrs/processors
    - Typical burden on chemical users minimal
      - Insure chemicals bought are on TSCA Inventory, and if subject to SNUR (not typical)

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"Core TSCA" (New & Existing Chemicals Program) Compliance Management

- Section 4 Test Rules
- Section 5 Premanufacture Notifications and Significant New Use Rules
  - Exemptions (R&D, LoRex, Polymer, et al.)
- Section 8 Reporting and Recordkeeping
- Import Certifications and Export Notifications

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Core TSCA Compliance Management

- Minimal Involvement with Supply Chain
  - Audits Internal Only
- Well understood by regulated community – program stable for 37 years
  - Regulated Community Has Good Compliance Track Record

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REACH Compliance Management

- REACH Not Only Imposes More Significant Burdens on Chemical Importers/Mfrs., but also on Downstream Users/Distributors, e.g.:
  - Operational Conditions and Risk Management Measures on Safety Data Sheet (SDS)
  - Chemical Uses Approved on SDS
  - Communications Required Up and Down the Supply Chain By All Parties

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REACH Compliance of Each Party In Supply Chain Dependent on other Parties

- Importers must obtain chemical identity information from foreign suppliers
- Foreign suppliers must obtain information from EU supply chain to set up “Only Representative”
- Importers/Manufacturers Need Use and Exposure Information to Prepare Registration Dossiers
  - For Intermediates, Confirmation That They Are Used Under Strictly Controlled Conditions
- Article mfrs. need to know SVHC constituents in raw materials

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Agreements with Suppliers and Customers

- Terms are likely to depend on relative market power of parties
  - A customer with substantial market power might be able to require a supplier to agree in the event of a restriction of the chemical that the supplier will use its best efforts to procure authorization for the customer's continued use
  - Making the customer an additional insured on the supplier's insurance policies might be required, as well as an agreement to indemnify against damages, claims or expenses (including attorney's fees) arising from breach of any warranty or representation, including those related to REACH compliance
  - Where the supplier has more market power, terms favorable to the supplier might be negotiated (indemnity in favor of the supplier)

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Compliance Audits

- A good compliance program is likely to be beneficial in obtaining favorable terms in an enforcement matter, and an audit component is likely to be viewed favorably, but:
  - Most companies would not permit the kind of audit that would be needed to verify REACH compliance, which would be intrusive
  - Given the complexities of supply chains, it would be extremely expensive and time consuming to audit all the suppliers in a supply chain
  - Other means to assure compliance may be viewed by the relevant enforcement authorities as sufficient, especially given that there is no audit requirement in the REACH Regulation

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Thank you for your attention!

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Risk Management and Liability

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REACH, Risk and Liability

- REACH is **about managing risks arising from chemical substances**

  BUT

- REACH is also **about managing risks arising from REACH itself**
  - **Legal risk management** is as important as physical risk management
- Legal risk can arise not just from non-compliance, but also from other activities or exposures driven by REACH compliance

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REACH Risks and Risk Management

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Legal Risks

- **Legal risks** resulting from REACH arise at several levels
  - Disproportional ECHA fees and compliance cost
  - Fines
  - Market withdrawal
  - Loss of market share
  - Loss of confidential business information
  - Civil liability
  - Reputational damage

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Internal Organization

- **Internal REACH compliance management** should:
  - Ensure **awareness** throughout the organization, including regulatory affairs, procurement, etc.
  - Clearly allocate **responsibilities**
  - Identify **all REACH obligations and risks**
  - **Document all decisions** made with the justification, for example, the decision not to register a substance because an exemption applies
  - Ensure proper **recordkeeping**
  - Cover **change management**

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Contracting

- **Contracts with suppliers and customers**
  - Contractual guarantees and/or certifications
  - "Due diligence" or "absence of *culpa*" defense may be available in enforcement action
  - "**Trust, but verify**": right to request information and to audit
- **Acquisition agreements**
  - REACH is a substantial potential liability risk
  - Representations/warranties, covenants, indemnities
  - REACH "due diligence" is often required in M&A

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Civil Liability

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European − US Liability Environment

- Europe's **civil liability environment** is very different from the US' liability regime:
  - In Europe, social security programs reduces incentives to file lawsuits
  - No class actions
  - No discovery
  - No jury trial
  - No punitive damages

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Product Liability

- EU Product Liability Directive
  - **No-fault liability** of producer for damage caused by **defective product**, which may involve **design** or **informational defect**.
  - **Supplier liability**: "Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer"
  - Defense: **State of the art defense** available in most, but not all, Member States

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Impact of REACH on Liability

- REACH may **decrease liability exposure**:
  - Companies **must analyze the hazards and risks of their chemicals and adopt measures to ensure safe use** of chemicals and products, which may result in **fewer accidents**, and, thus, reduced exposure
  - Product that is "**safe**" or is accompanied by the necessary information to be "**safely used**" under REACH may ***de facto*** **be regarded as not being "defective"**

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Impact of REACH on Liability

- REACH may also **increase product liability** exposure:
  - REACH requires **disclosure of information** on the basis of which **claims** could be asserted, including in the **US**
  - REACH **raises the applicable standards** by requiring all chemicals and products to be "**safe**," and **not** pose any **inadequately controlled risk**
  - **Non-compliance with REACH** may constitute **negligence *per se***, which may trigger liability

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Thank you for your attention!

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Product Liability & Regulatory Process

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Product Liability & Regulatory Process

- While Chemical Regulatory Regimes do not set forth liability rules for personal injury or property damage caused by chemicals, they are important to consider in formulating product defense strategies
  - They require various public disclosures and filings with government agencies respecting chemicals that are relevant in litigation arising from allegations that such chemicals have caused personal injuries and/or property damage
  - Impact is not only in the country whose regulatory regime has required the disclosure of filing, but in other jurisdictions

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Product Liability & Regulatory Process (cont.)

- Regulatory determination may impact determinations of civil or criminal liability in other contexts
  - REACH determination that a chemical use poses an "unacceptable risk" or a risk "not adequately controlled" could be problematic in a civil liability matter involving personal injury or property damage arising from such use
  - Violation of chemical regulation could serve as basis for determination of negligence, gross negligence, intentional tort
    - Duty of care
    - Duty to warn

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Product Liability & Regulatory Process (cont.)

- General issue respecting the volume and diversity of data and document necessitated by chemical regulatory regimes
  - All available in civil litigation; discovery in US
  - Fodder for experts (hired guns)
- Need to be mindful of competitors' filings and disclosures for same chemicals

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Corporate Management Of Chemical Laws

Michael P. Walls
Vice President, Regulatory & Technical Affairs

American® Chemistry Council

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Managing the Chemical Trends

- Fundamental value of knowing the company and the product
- Prioritize compliance efforts
- Understand regulatory requirements
- Have the necessary science
- Align information resources: Agencies, associations, consultants, outside counsel

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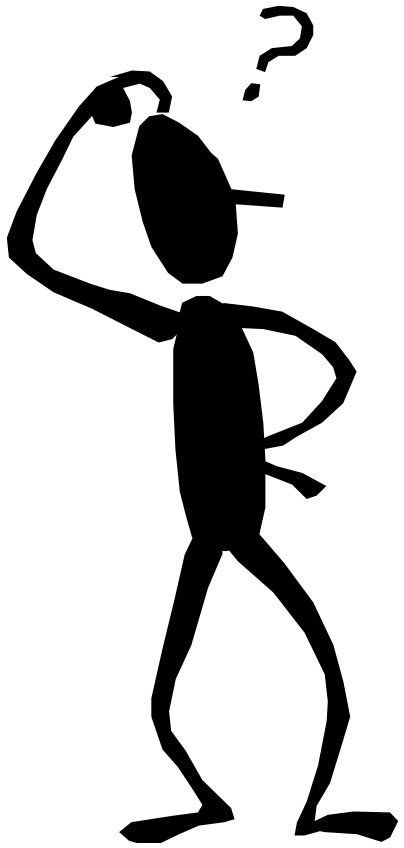
Address the Challenges

- Protecting Market and Reputational Interests
- Protecting Confidential Information
- Hazard and Exposure Evaluations
  - Critical role of exposure information
- Resources
- Active engagement in advocacy
  - TTIP signaling coherence opportunities
  - TSCA reform as a REACH alternative

Questions?



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Thank You

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