Strategies for Complying With the Increasing Complexity of Chemical & Product-Based Environmental Regulations in the Global Marketplace

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Welcome & Introductions

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Congressional Efforts to Reform TSCA

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US EPA’s New Approach Under TSCA

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Toxic Substances Control Act (TSCA)

• Enacted in 1976
• Applies to chemical manufacturers, importers and processors
• Covers chemical substances and mixtures, but does not regulate:
  ➢ Substances that are regulated as pesticides under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA)
  ➢ Drugs, cosmetics and other items regulated under the Federal Food, Drug & Cosmetic Act (FFDCA)
  ➢ Material regulated under the Atomic Energy Act (AEA)
  ➢ Tobacco and tobacco products
  ➢ Articles taxed under §4181 of the Internal Revenue Code (firearms & ammunition)
• Requires EPA to coordinate with, and sometime defer to action by, other federal agencies (e.g., FDA, CPSC)
TSCA Requirements

• In general, if a chemical substance is not listed on the TSCA Inventory, it cannot be produced, distributed, sold or imported in the US.
  ➢ Roughly 85,000 substances are listed on the TSCA Inventory

• With certain limited exceptions, any person who “manufacturers for commercial purpose” any “new chemical substance” must file a premanufacture notice (PMN) for that substance with US EPA.
  ➢ A “new chemical substance” is any substance that is not listed on the TSCA Chemical Substance Inventory (TSCA Inventory)
  ➢ EPA has 90 days to review a PMN
TSCA PMN Exemptions & Exceptions

• Exemptions
  ➢ Research and development (R&D)
  ➢ Low volume (LVE)
  ➢ Test marketing (TME)
  ➢ Low environmental release and human exposure (LoREX)
  ➢ Certain polymers

• Exceptions
  ➢ Mixtures
  ➢ Imported Articles
Key TSCA Provisions

• **Section 5: Manufacturing and Processing Notices**
  - PMNs & SNURs

• **Section 6: Regulation of Hazardous Chemical Substances and Mixtures**
  - Authorizes EPA to take a range of actions to control a chemical hazard that “presents or will present an unreasonable risk of injury to health or the environment.”

• **Section 4: Testing of Chemical Substances and Mixtures**
  - Gives EPA authority to require the development of test data on existing chemicals

• **Section 8: Reporting and Retention of Information**
  - § 8a reporting
  - § 8d health & safety studies
  - § 8c records of significant adverse reactions to health or the environment alleged to have been caused by the substance or mixture
  - § 8e “substantial risk” information

• **Section 12: Exports**

• **Section 13: Imports**
Recent EPA Actions under TSCA

- Ten Action Plans issued
- Section 4 Test Rules (issued/proposed)
- Section 5 Significant New Use Rules (SNUR) (proposed) for several existing chemicals
- New Chemical Data Reporting (CDR) Rule (August 2011)
- Priority list of 83 “work plan” chemicals announced for risk assessment and potential risk management (March 2012)
- Proposed rules on formaldehyde in composite wood products issued (May 2013)
In March 2012, EPA released a list of 83 priority “work plan” chemicals identified for risk assessment and potential risk management actions

- EPA first identified 1,235 chemicals identified as potentially of concern for children’s health, as persistent, bioaccumulative or toxic (PBT), or as probable or known carcinogens.
- EPA then developed a list of 345 chemicals by excluding chemicals regulated under federal laws (such as pesticides and drugs), chemicals that generally do not present significant health hazards (such as polymers), and chemicals already extensively regulated (such as PCBs).

Final list reduced to 83 chemicals by assigning scores based on three characteristics: (i) hazard; (ii) exposure; and (iii) potential for persistence and/or bioaccumulation.

- The list includes chemicals that may not present human health concerns but met all criteria for identification as persistent, bioaccumulative and environmentally toxic chemicals.
Work Plan Risk Assessments

• Seven chemicals identified for risk assessment in 2012

• Draft risk assessments on five of the chemicals released for public comment in January 2013:
  - Antimony Trioxide (ATO) (CASRN 1309-64-4):
  - 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran (HHCB) (CASRN 1222-05-5):
  - Methylene Chloride (or dichloromethane (DCM)) (CASRN 75-09-2):
  - Trichloroethylene (TCE) (CASRN 79-01-6):
  - N-Methylpyrrolidone (NMP) (CASRN 872-50-4):

• Risk assessments on long-chain chlorinated paraffins and medium-chain chlorinated paraffins to be released later this year

• Eighteen additional chemicals will undergo risk assessments in 2013 and 2014

• Additional group of flame retardants also targeted for review and risk assessments
Increased TSCA Enforcement

- **EPA is increasing enforcement activity under TSCA**
  - Increased use of TSCA subpoenas for investigations
  - Focus on TSCA § 5 violations (PMNs; SNURs & SNUNs; LVEs)
  - Target reporting and record keeping under TSCA 8(c), (d) and (e)
  - Focus on the Chemical Data Reporting (CDR) Rule

- **February 2012:** $1.4 million civil penalty announced against Dover Chemical Corp. for alleged failure to file premanufacture notices (PMNs) for chlorinated paraffins it was manufacturing.

- **July 2012:** Penalties totaling $362,113 announced against Chemtura Corporation, Bethlehem Apparatus Company, and Haldor Topsoe, Inc. for violations of the 2006 Inventory Update Reporting rule (now the CDR rule).

- **August 2012:** $175,000 civil penalty announced against INEOS for alleged importation of paraffins not listed on the TSCA Inventory.

- **January 2013:** $503,110 civil penalty announced against Kemira Chemicals, Inc. for violations of the 2006 IUR rule.
FIFRA Requirements

• Federal Insecticide, Fungicide & Rodenticide Act (FIFRA)
• No pesticide product can be manufactured, distributed, used or imported in the United States unless it has been registered with EPA.
• Definition of “pesticide” includes “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”
• “The label is the law”
  ➢ Pesticide can be marketed only for the uses approved by EPA and specified on the product’s label.
• Mandatory ongoing obligation under FIFRA section 6(a)(2) to provide “adverse effects” information to EPA.
Pesticidal Intent & Pesticidal Claims

- Whether a product is a pesticide under FIFRA depends in part on “pesticidal intent” – i.e., whether the manufacturer, distributor or seller of the product states or implies that the product prevents, destroys, repels or mitigates a pest.
  - A product may not be considered a pesticide by EPA, even if it has a pesticidal effect, as long as no pesticidal claim is made – but only if no pesticidal claim is made
  - Includes claims made on the product label or through other means such as websites, advertising, promotional or sales activities and testimonial claims in connection with the sale or distribution of the product.
Pest Control Devices

• “Pest control devices” are regulated under FIFRA but are NOT required to be registered with EPA
  ➢ A product is a pest control device if it uses only physical or mechanical means to trap, destroy, repel, or mitigate any pest and does not include any pesticidal substance.
  ➢ A device that incorporates a pesticide, or is used with a pesticide, must be registered.
  ➢ If a device and a pesticide product are packaged together, the combined product is a pesticide product subject to registration requirements.
  ➢ Devices whose effectiveness depends more upon the performance of the person using them than on the performance of the device itself, or that operate to entrap vertebrate animals, are not regulated at all (e.g., fly swatters, mousetraps).
A Primer on Consumer Products Regulation

Allen Kacenjar
Cleveland
A Whole Different World

• Involves different federal agencies –
  ➢ Consumer Product Safety Commission (CPSC)
  ➢ Federal Trade Commission (FTC)
• Broader than most companies recognize
• Real emphasis by Obama Administration
• Substantially increased enforcement profile
Federal Hazardous Substances Act (FHSA)

• Older, but still important:
  
  CPSC “will aim resources at FSHA enforcement” because we “need to circle back around and enforce and make sure that manufacturers are still compliant.”

  - CPSC Executive Director, Kenneth Hinson

• Applies to “hazardous substances intended or packaged in a form suitable for use in the household.” Three threshold requirements:

  1. **Household Product**
  2. **Must contain hazardous substances**
  3. **Must have the potential to cause injury or illness**
FHSA Regulatory Thresholds

• What are “household products”?
  ➢ “Customary and reasonably foreseeable” standard.
  ➢ Broadly construed to includes garages, sheds or other buildings that are part of the household.
  ➢ Jurisdictional guidance on a product-specific basis

• What are “hazardous substances”?
  1. Toxic (injury or illness of inhaled, swallowed or absorbed)
  2. Corrosive (destroys living tissue)
  3. Irritant (substantial injury short of destroying tissue)
  4. Strong sensitizer (hypersensitivity)
  5. Flammable
  6. Generates Pressure (explosion, decomposition, etc.)

• What risk triggers regulation?
  ➢ Little formal guidance, but consider
    – How contents and form of product might cause injury
    – Intended handling, use and storage
    – Foreseeable accidents, especially involving children
FHSA – Key Implications

• **Detailed Labeling Requirements**
  - Must be “conspicuous”
  - Contact information
  - Names of hazardous ingredients
  - Affirmative warnings of principal hazards
  - Special care/handling instructions

• **Limited Product Bans**

• **Compliance & Enforcement Risk**
  - Obligations placed on the regulated community
  - CPSC will provide guidance on jurisdictional issues
  - Will also provide informal comment on proposed labels
Consumer Product Safety Improvement Act (CPSIA)

• **Scope and Purpose:**
  - Significantly expanded CPSC’s authority and increased its resources
  - Covers anyone making, producing or assembling a consumer product
  - Broadly applies to consumer products, with a particular focus on children's products
  - Expanded enforcement authority:
    - State attorney’s general authorized to initiate actions in federal court
    - Stricter civil penalties - $100K per violation and up to $15 million

• **Key Provisions:**
  - Banned children’s products exceeding specified lead levels
  - Set 90 ppm limit for lead in paint
  - Banned certain phthalates from certain children’s toys and products
  - Required manufacturers (including importers) to certify compliance – primarily based on third-party laboratory testing.
  - Public database on consumer product safety with “reports of harm”
  - Required tracking labels to enhance “recall-ability”
CPSIA – Problems & Amendments

• **Unintended Consequences:**
  - CPSC unable to issue flood of necessary regulations
  - Gridlock, risk adverse decisions and economic harm

• **August 2011 Amendments:**
  - “Getting the lead out” changes
    - 100 ppm limit no longer retroactive
    - Allows commission to consider risk and grant exemptions
    - Excludes certain products (bikes, ATVs, used products)
    - “Functional purpose” exemption upon CPSC approval
  - Required solicitation of comment on ways to reduce cost of testing and authorized alternatives for small batch manufacturers
  - Focused phthalates ban on accessible parts
  - Tweaks to the database requirements – more time before posting
CPSIA – Key Developments

• **Certification Rules Now in Force**
  - November 8, 2011 final rule applies to products manufactured on or after February 8, 2013. Key elements include:
    - Third-party testing of a “sufficient” number of samples
    - Must be repeated periodically and when there are material changes
    - Burdensome recordkeeping requirements
  - Ability to rely on component testing – with “due care”, but manufacturer still responsible.

• **Transition to Enforcement:**
  - Bulk of rulemaking is finally complete
  - “This commission should use all of its resources and its legal opportunities to enforce our laws.” - Chairman Inez Tenenbaum

• **Practical Advice:**
  - Proactively assess coverage
  - Know your suppliers and develop strong agreements
  - Address concerns before the CPSC does
Green Guides

• The first step in FTC’s “multi-tiered approach” to combating a “tsunami of environmental marketing.”
  ➢ Establishes clear “rules of the road” for businesses
  ➢ To be followed by enforcement directly challenging fraudulent and deceptive environmental advertising
  ➢ Also launching a consumer information campaign
    - James A. Kohm, FTC Associate Director of Enforcement

• Explains what constitutes deceptive environmental marketing under Section 5 of the FTC Act.
  ➢ “Likely to mislead consumers acting reasonably under the circumstances and is material to consumers’ decisions.”
  ➢ Guidance – not regulations.
Green Guides

• **Scope:**
  - Applies to claims about the environmental attributes of a product, package or service offered for sale.
  - Expressly covers business-to-business transactions
  - Reaches labeling, advertising, promotional materials and “all other forms of marketing in any medium” whether “directly or by implication, through words, symbols, logos, depictions, product brand names….”

• **Test:** How will reasonable consumers likely interpret the claims?
  - Focuses on consumers in your target market.
  - Includes “all reasonable interpretations” of claims
Green Guides

• Guiding Principles
  ➢ General claims strongly discouraged – be specific
    ➢ “Environmentally preferable” or “Eco-friendly”
  ➢ “Technically true” isn’t enough
  ➢ Substantiation is necessary
  ➢ Ensure the benefit is not legally required

• Strategic Advice
  ➢ Start early in the process
  ➢ Document, document, document….
  ➢ Watch for inconsistencies (e.g. ISO 14021)
  ➢ Keep an eye on the market
California’s Green Chemistry Initiative: Being Green Could Cause Some Companies To See Red

Chris M. Amantea
Los Angeles
Why Should You Be Concerned?

A sage lawyer, once opined…

“Kermit the Frog seems to have had it right when he warbled his catchy little tune lamenting the perils of being green; although he might soon be singing a new ditty called ‘Is that red, I’m seeing?’”
Traps For The Unwary…Or The Unaware

- Safe Drinking Water & Toxic Enforcement Act (Proposition 65)
- Safer Consumer Product Regulations (Green Chemistry Initiative)
- California Phthalates Law (AB 1108)
- California Toxics In Packaging Prevention Act (AB 455)
- Disproportionate impact on out-of-state national or multi-national companies doing business in California
Proposition 65 Overview

- Applicable to businesses with **10 or more employees**
- **KEY ISSUE:** *exposure* to substances which cause **cancer or reproductive toxicity**
- Exposures can occur through **consumer products, the environment, or the workplace (occupational)**
- **PRIMARILY:** A warning and labeling law. Prior to exposing individuals, **clear and reasonable warnings** must be given
Proposition 65 Thresholds

- Reformulation of products or strict adherence to low (and, in some cases, unrealistic) threshold concentrations of targeted chemicals.
- Proposition 65 establishes low “safe harbor” concentrations for certain chemicals in products.
- The list of Proposition 65 chemicals – over 800 chemicals! Will be used for identifying Candidate Chemicals under the Safer Consumer Product (Green Chemistry) regulations.
Penalties Can Be Significant

• The law is enforced by the California Attorney General and by County District Attorneys

• **Bounty Hunter Provision:** *Any person*, after issuing a 60-day notice of violation (when no public prosecutor is pursuing action) can bring an action. They receive a % of settlement or judgment

• Penalties up to $2,500 per exposure per day

• Injunctions may be obtained to prevent threatened or recurring violations
California Green Chemistry Initiative

- Became law in September 2008
- On July 27, 2012 State issued first regulations under the initiative: Safer Consumer Products Regulations
- Prevailing view is that regulations will be finalized by October 2013
- **Goal of legislation**: Cause reformulation of possibly hundreds of thousands of consumer products sold or distributed in California OR ban their sale, manufacture, import, or distribution in California

“[t]he proposal requires manufacturers to seek alternative ingredients in widely used products, offering California industry the opportunity to lead the way in producing safer versions of goods already in demand around the world…[i]f an alternative is not feasible, DTSC will identify the steps the manufacturer must take to ensure the product is safely used, disposed of, or phased out.”

(DTSC, July 2012)
Why You Should Care…

- Will have significant impact on virtually all companies manufacturing, selling, or distributing consumer products in California
- The **number of consumer products** potentially covered is huge
- **Four-step implementation process** proposed by DTSC is expensive, time consuming, and cumbersome
- **Trade secret** information may be publicly available
Why You Should Care…

• **Conflicting regulatory schemes** (e.g., TSCA, REACH, CPSIA, Proposition 65, to name a few).

• Potential impact of TSCA Reform and preemption

• Some of the conflicting issues:
  - Scope of products/chemicals covered?
  - Threshold levels?
  - Issues associated with reformulation?
  - What are the competitors doing?
How We Can Help…

• Assist with evaluating the complexities of the proposed Safer Consumer Products Regulations and how they might impact your business, considering overlapping and conflicting international, national, and state regulatory requirements

• Help with navigating through various strategic alternatives in implementing the regulations, once they are adopted

• Assist in evaluating and revising existing agreements with suppliers, vendors, manufacturers, distributors, or retailers to account for new regulatory requirements
REACH – What are the real liabilities?

Dave Gordon
UK/Europe
Overview

• An overview of REACH
• The legal issues – lessons learned:
  ➢ Supplier obligations.
  ➢ Downstream user rights.
  ➢ Consumer rights.
  ➢ Enforcement.
Overview - Why REACH?

• Under the old chemicals legislation, “existing” chemical substances (marketed before 18th September 1981), did not need to be notified/registered i.e., basically no data on 99% of substances present on the EU market

• 1993: introduction of reporting system for “existing” substances – it never really took off

• REACH implemented to deal with the “Burden of the Past”

100,106 “existing substances” only a few dozen evaluated
Overview - REACH basics

A single, integrated system for the Registration Evaluation Authorization of Chemicals
Overview - REACH Registration

• All substances manufactured or imported (on their own or in preparations) in the EU > 1 t per year must be registered in a central database (managed by the European Chemicals Agency -ECHA).

• Timeline and data package dependent on volume and toxicity.

• Information required on:
  – Intrinsic properties of substances (e.g., physiochemical, toxicological and ecotoxicological properties) – may require new testing when adequate data is not available.
  – The use(s) of the substances by the importer/manufacturer or their customers.
Overview – REACH Evaluation

| Dossier Evaluation | • To be carried out on all animal testing proposals to ensure that unnecessary testing is avoided.  
|                    | • Spot checks for compliance with Registration requirements. |
| Substance Evaluation | • To be performed when there is a reason to believe that a substance may pose a risk to  
|                    | • Human health or the environment.  
|                     | • ECHA prioritization may lead to product deselection. |
| Result             | • May lead to Authorization/Restrictions |
Overview - REACH Authorization (1)

Substances deemed of very high concern

- CMRs (carcinogenic, mutagenic or toxic to reproduction) category 1 and 2
- PBTs (persistent, bio-accumulative and toxic)
- vPvBs (very persistent, very bio-accumulative)
- Scientifically proven to have a similar effect, e.g. endocrine disrupters
- There is now a “candidate list” published containing 72 substances
  Beware of “black list” effect
### Authorization

- Manufacturer/importer/downstream user makes application.
- Decision prepared by Agency and adopted by Commission.
- Applies to specific uses.
- Reverse burden of proof:
  - Proof that risk is adequately controlled; or
  - Proof that the socio-economic benefits outweigh the risks and there is no suitable alternative substance or technology.
Overview - REACH Authorization (2)

Conditions for Restriction

- “unacceptable risk to human health or the environment arising from the manufacture, use and/or placing on the market of substances”

- Decision must take into account the socio-economic impact of the restriction, including availability of alternatives.
Overview - REACH Timeline

• June 2008-November 2008: pre-registration of “phase in”
• June 2009: publication of “priority substances” for authorisation
• November 2010: registration for substances imported/manufactured in quantities of 1,000 tons or more (+certain substances of concern)
• June 2013: registration for substances imported/manufactured in quantities of more than 100 tons or more
• June 2018: registration of substances imported/manufactured in quantities of one ton or more
Legal issues - Supplier Obligations

• Article 33 requires Suppliers of Articles containing SVHC above 0.1% w/w to provide customers with sufficient information to allow safe use including (as a minimum) the name of the SVHC.

Question 1: on import of a car in to the UK is the car the Article or is each of its components an Article e.g. the steering wheel?

Question 2: on supply of a product containing a SVHC can the supplier just refer the customer to a website for REACH related information?

• Article 31 requires Suppliers to provide the recipient of any dangerous Substance or Preparation with a Safety data Sheet to allow safe use and handling.

• Article 7.2 also requires importers and manufacturers to Notify EHCA of Articles containing SVHC above 0.1% w/w in quantities above 1 t/yr.
Legal issues – Downstream User Rights/Obligations

- REACH does not require manufactures to support all uses.

**Question**: is a Downstream user in breach of REACH if supplied with an unregistered substance?

- Downstream user must comply with the requirements of SDSs.

- Authorisation is supply chain specific.
Legal issues - Consumer rights

- Under Article 33.2 – Consumers can demand information relating to the presence of hazardous substances in articles so to allow safe use.

- It’s apparent that many companies are still not exactly sure of what they are selling and are struggling to meet the above requirement.

- Interestingly, in a recent European consumer survey performance seemed to depend more on country than on company:

**Question**: Pick the best and the worse in the following jurisdictions:
Austria, Denmark, France, Germany, Greece, Poland, Spain, Sweden and the UK.
Legal issues - Consumer rights under REACH
Legal issues - REACH Enforcement

- At European level the European Chemicals Agency (ECHA).
- Failure to pre-register/register result in **loss of EU market...no data, no market!**
- Penalties should be consistent across the EU but are at the Member State’s discretion and must be fair and proportionate.

**Question:** What’s the highest level of fine and where?
- No due diligence defence.
- Existing legislation still applies e.g. COSHH.
Co-ordination across EU by the Forum for the Exchange of Information:

- Belgium – Fines between £1k to £22M & imprisonment  8 days to 3 years.
- France – Fines between £15K to £375K & imprisonment 2 months to 2 years.
- Italy – Fines between £5K - £120K. No imprisonment.
- Netherlands – Fines up to £74K. No imprisonment.
- Spain – Fines up to £1.2M & imprisonment 3 months to 3 years.
- UK – up to £5,000/3 months and on indictment unlimited/2 years

Inspections

- France – 317 inspections.
- Italy – 2 inspections.
- UK – 500 plus.
- Germany – 279 inspections.

Notices

- UK – 44 Improvement Notices (mostly failure to register), 5 Enforcement Notices (enforcing restrictions) and 1 Prohibition Notice (dichromate ban).
- France – 16 enforcement notices.
- Cyprus – 7 prosecutions.
- Germany – 57 violations.
- Italy – 0 prosecutions.

Question: what’s the average inspection failure rate across the EU?
Examples of typical requests:

- Reviewing supply chain and presence of SDSs.
- Reviewing companies internal REACH protocols/procedures.
- Investigating processes that use SVHC.
- Interviews with REACH ‘responsible person’.
- Review of permits/EMS.
- Request/review of list of substances.
- Downstream users are being asked for certificates of compliance from supplier.
- UK has an inspection based approach. Select a substance, check who imports/manufacturers it and compare names with registrations.

Be prepared - develop an inspection manual (Article 36), make sure documentation is ready and know local requirements/priorities. Cooperate but protect confidential info./stand up for your rights!
Legal issues – Enforcement trends

Some recent examples:
- SVHC disclosures – 50% of retailers don’t answer at all and 28% gave inadequate answers
- Substances misclassified - then incorrectly pre-registered/ registered.
- Only Representative sanctions – 2 OR appointed illegally by distributors are currently being prosecuted. Up to 9,000 pre-registrations at risk.

The EU regulator approach – is considered and helpful:
- Focus on securing compliance and using NOT prosecution.
- Case by case approach.
- Account for individual circumstances.
- Often extensions granted.
- Likely to change as time passes.

Other recent developments:
- Using REACH to gain an competitive advantage.
- An increase in transactional warranty claims
- NGO intervention based on toxicology data.
Questions

...???
Issues & Strategies

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