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K&L Gates Webinar

Chemical Regulations: A Legal Primer

May 5, 2015

AGENDA

- Overview of Federal Chemical Regulation
- What's next for the United States Congress? Is this the year for TSCA reform?
- California Chemical Regulation Issues – Impacting the U.S. Nationwide
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Introduction of Presenters

PRESENTERS



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Overview of Federal Chemical Regulation



David Naidu
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TSCA

- What is regulated under TSCA?
 - “Chemical substances” and “mixtures”
 - Chemical substance: “any organic or inorganic substance of a particular molecular identity”
 - Mixture: “any combination of two or more chemical substances if the combination does not occur in nature and is not ... the result of a chemical reaction”
 - Portions regulate articles containing chemical substances
 - Pesticides, nuclear materials, food and drugs exempt
- Who is regulated under TSCA?
 - “Manufacturers,” including importers and exporters
 - “Processors” who prepare chemicals for distribution

TSCA: NEW CHEMICAL REGULATIONS

- TSCA § 5 regulates “new chemicals” not listed on TSCA inventory and new uses of listed chemicals
- Pre-Manufacture Notice (PMN) for manufacturers
 - Must notify EPA and provide information about new chemical 90 days before manufacture
 - Exemptions: non-commercial R&D, <10,000 kg/year, etc.
- Significant New Use Rule (SNUR) for manufacturers and processors
 - EPA promulgates SNUR when chemical on TSCA inventory is put to new use
 - If subject to SNUR, must provide notice similar to PMN

TSCA: OTHER PROVISIONS

- § 4: Testing requirements
- § 6: EPA can restrict chemicals presenting an unreasonable risk of injury to health or the environment
 - EPA has used § 6 sparingly (asbestos, hexavalent chromium, certain metal-working fluids, and statute itself addresses PCBs)
- § 7: EPA can initiate judicial action to seize or enjoin manufacture of chemical presenting “imminent risk”
- § 8: Recordkeeping
 - Maintain records of allegations of significant adverse reaction and notify EPA after receiving information that chemical presents a substantial risk

EPCRA

- Emergency Planning
- Emergency Release Notification
- Reporting to state and local government
- Toxic Release Inventory

RCRA

- Requirements based on amount stored
- Generator Identification Number
- Manifests
- Recordkeeping

EXAMPLES OF TSCA APPLICATION

- Application of TSCA to imports
- Application of TSCA to nanomaterials
- Proposed TSCA regulations and current state rules on disclosure of hydraulic fracturing chemicals

TSCA IMPORTS

- TSCA's definition of "manufacture" includes importation
- § 13: Chemical importer must certify TSCA compliance
- Who is the "importer"?
 - Under customs regulations, person primarily liable for duties
- Chemicals contained in "articles" are not covered
 - Items that do not change chemical composition in end use or whose composition change does not create commercial product (e.g., paint, fuel, batteries)
- Importer must certify compliance with TSCA through a certification
 - Is the chemical on TSCA Inventory or not?
 - Does a SNUR apply to this chemical?

TSCA -- NANOMATERIALS

- What are nanomaterials?
 - Structures with dimensions of 1-100 nanometers that have unique properties due to their relatively larger surface area to mass ratio as compared with conventionally-sized substance.
- EPA does not consider nanoscale version of listed chemical a “new chemical” automatically, but compares molecular identity of conventional listed substance with nanoscale substance
- Nanoscale Materials Stewardship Program (2008-2009)
 - Voluntary program in which EPA asked manufacturers to submit information on exposure, fate, and toxicity of nanomaterials
 - EPA received data on only 10% of commercially available nanomaterials
- March 2015: Proposed rule under TSCA § 8(a)
 - EPA will mandate previously voluntary disclosures from NMSP

PROPOSED § 8(A) RULE FOR NANOMATERIALS

- Must report volume produced, occupational or general public exposure, estimated amounts released, and existing data on environmental and health effects
- Separate reporting for “discrete forms” of chemical substance
 - There is (1) change in process to effect size or properties, (2) >10% change in particle size, and (3) significant change in other properties considered relevant to health and safety
- Exemptions and exclusions
 - R&D, small manufacturer (sales < \$4 M), same information already reported under NMSP, biological materials (e.g., DNA), zinc oxide
- Timing of required data submission
 - Current manufacturer/processor: within six months of final rule
 - Future manufacturer/processor: at least 135 days before beginning production

DISCLOSURE OF HYDRAULIC FRACTURING CHEMICALS

- May 2014: EPA proposed rulemaking under TSCA § 8 to mandate disclosure of chemicals used in hydraulic fracturing
- Proposal would require disclosure of name, CAS No., and concentration of each chemical used
 - Open question: Can TSCA rule apply to drillers rather than chemical producers? A driller may not be a “manufacturer” or “processor” of chemical.
- March 2015 BLM final rule for drilling on federal & tribal lands could hint at how EPA may address hydraulic fracturing under TSCA
 - Chemical information can be disclosed through FracFocus
 - Well operator and third-party “owner” of trade secret must provide affidavit
 - Evaluate trade secret claims under standard from federal FOIA case law
- Issues raised by proposed TSCA rule have arisen at the state level
 - When EPA enacts final rule, TSCA § 8 regulations would not preempt state law

DISCLOSURE OF HYDRAULIC FRACTURING CHEMICALS

- Three states require disclosure of actual concentrations of chemicals used in hydraulic fracturing fluid to regulators
 - Required by EPA TSCA proposal, but most state disclosure regimes require maximum possible, not actual, concentrations
- Regulated entities claim that identities and concentrations of chemicals are trade secrets that cannot be disclosed under public records laws
- Environmental groups sued Wyoming agency that did not disclose asserted trade secrets

DISCLOSURE OF HYDRAULIC FRACTURING CHEMICALS

- *Powder River Basin Resource Council v. Wyoming Oil & Gas Conservation Commission* (Wyo. 2014)
 - Court evaluating state's protection of trade secret will make an independent determination in each case and not defer to agency
 - “Narrow” definition of trade secret: (1) secret, (2) commercially valuable, and (3) the end product of innovation or substantial effort
 - BLM will use a similar trade secret definition for drilling on federal land
 - Remanded to decide trade secret claims based on this standard
- Settlement reached in January 2015
 - State adopts new guidelines for claiming trade secrets and companies with disputed trade secrets must resubmit
 - Providing information on each ingredient in an additive or providing separate lists of ingredients and additives

What's next for the United States Congress?
Is this the year for TSCA reform?



Cliff Rothenstein
Washington, DC

DÉJÀ VU ALL OVER AGAIN?

- TSCA was enacted in 1976 and signed into law by President Ford.
- In 40 years it has never been reformed.
 - TSCA allowed 62,000 chemicals to stay on the market unless EPA found they pose and “unreasonable risk”.
 - In 1991, EPA’s asbestos ban was struck down because costs were not fully considered.
 - EPA has ordered testing of about 250 (of the now 84,000 chemicals in use) and restricted or banned 9.
- Consensus that it has not worked well ... so states have filled the void.
- Thirty-three state governments have adopted measures restricting the use of individual chemical substances in the place of action from the Federal government. These chemicals include: BPA, formaldehyde, lead, mercury and flame retardants.

RECENT ATTEMPTS TO REFORM TSCA

- Aborted attempts over last several years to reform TSCA:

2010 legislation

- Senator Lautenberg (S.3209)
- Rep. Waxman and Rush (H.R. 5820)

Bills would have shifted burden of proof from EPA to manufacturers; increase public access to information and require EPA early chemical evaluations.

2012 legislation

- Senator Lautenberg (S. 696 and S. 1009)

Bills requires categorization of new and existing chemicals; assignment of priorities for safety assessments; preemption of state laws that require similar testing as required by EPA and after a chemical assessment is completed.

THE LATEST ATTEMPT TO REFORM TSCA - 114TH CONGRESS

- Vitter-Udall (S.697) “The Frank R. Lautenberg Chemical Safety for the 21st Century Act”
 - 16 bipartisan cosponsors
 - Supported by chemical industry, EDF; some state chemical regulators
 - Approved by a vote of 15-5 by EPW Committee on April 28, 2015
- Boxer-Markey (S. 725) “Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act”
 - Supported by public health and environmental interest groups, some AGs
- Shimkus – Discussion draft (April 7, 2015)
 - House Energy & Commerce Subcommittee Markup scheduled for May 14, 2015
 - General bipartisan support

TSCA BILL COMPARISON

Major Provisions	Frank R. Lautenberg Chemical Safety for the 21 st Century Act S. 697 (Vitter-Udall)	Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act S. 725 (Boxer-Markey)	TSCA Modernization Act of 2015 (House Discussion Draft April 7, 2015 (Shimkus)	Current Law 15 USC § 2601-2692
New Chemicals	All new chemical substances (and significant new uses) subject to a safety determination before they may enter commercial production.	All new chemical substances (and significant new uses) would be subject to a safety determination before they may enter commercial production.	No changes to current law.	Requires submission of pre-manufacture notice but no affirmative safety decision
Existing Chemicals	Requires a safety review of all chemicals in commerce according to priority classification. Requires EPA to initially list 10 high priority chemicals for assessments, add additional chemicals and ensure at least 25% have been assessed in 5 years. EPA given up to 3 years for safety assessment and determination for high priority chemicals and up to 2 years to issue final rule, with a 2 year extension possible.	Requires safety review of all chemicals according to priority classification. Requires initial review of 15 high priority chemicals adding 15 per year for 4 years. EPA must complete safety assessment and determination for high priority chemicals within 2 years from listed, and issue a final rule within 2 years with a 2 year extension.	Requires risk assessment for chemicals if EPA finds a reasonable basis that a chemical can present an unreasonable risk within 3 years, or within 180 days if a manufacturer (who is willing to pay the EPA administrative cost of the evaluation) request an evaluation. EPA given 180 days from publication of assessment to issue final rule with 2 year extension. No number of chemicals outlined.	No mandate to review and no criteria for triggering a review for an existing chemical.
Safety Standard	Unreasonable risk but precludes EPA from considering cost and other non-risk factors in making safety determinations	Reasonable certainty of no harm without taking cost or other non-risk factors into consideration	Unreasonable risk in the absence of requirements	Unreasonable risk determination and cost-benefit analysis
Preemption	Grandfathers existing state laws adopted prior to 8/1/15, but preempts states from new laws after EPA defines the scope of a safety assessment for a high priority chemical until EPA publishes a safety assessment and determination (5 year preemption period). Allows states to implement and co-enforce identical chemical regulations; states could not impose greater penalties for violations than federal law allows; either state or federal government, but not both could collect the penalties	No preemption	Preemption after final decision by EPA either in a rule managing risk making or decision that the chemical does not pose a serious risk.	Preemption of state and local regulation after EPA issues rules or order.
Articles of Commerce	Allows EPA to authorize restrictions to chemicals in articles only to the extent necessary to address the identified risks in order to determine chemical meets the safety standard. EPA may apply a SNUR to chemicals in articles only if agency makes a finding that the reasonable potential to the chemical through the article warrants notification	Requires import certification for chemicals in articles subject to regulation under TSCA section 5 and 6	Articles would be treated through normal assessment process for existing chemicals.	Articles containing chemical substances designed to be used or released subject to TSCA otherwise they are generally exempt. EPA may exempt or require articles from SNURs
Fees	User fee program would be implemented to cover cost of reviewing chemicals.	A user fees is established with a significantly larger proportion of EPA actions would be funded with user fee.	Manufacturers would be able to designate chemicals for risk evaluation and then provide a user fee for this evaluation.	No fee structure for users. Funding from EPA only.

STAKING OUT POSITIONS - THE PLAYERS

Senator James Inhofe (R-OK) Senator Barbara Boxer (D-CA) Senator Tom Udall (D-NM) Senator David Vitter (R-LA)



Rep. Mark Takano (D-CA)



Rep. Fred Upton (R-MI)



Rep. Frank Pallone (D-NJ)



Rep. John Shimkus (R-IL)

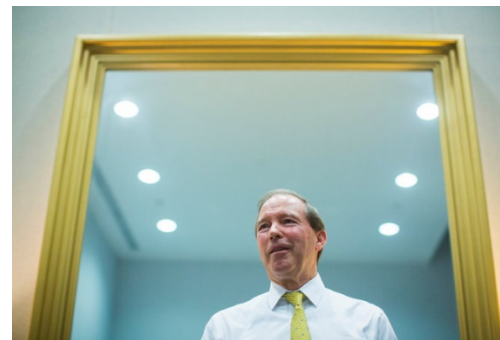


STAKING OUT POSITIONS - THE PLAYERS



The New York Times

Tom Udall's Unlikely Alliance With the Chemical Industry



STAKING PUT POSITIONS – THE ISSUES



STAKING OUT POSITIONS – KEY ISSUES

- **Preemption** - Timing of preemption - Is there a “death zone”?
- **Safety Standard** - Does it pass asbestos laugh test? Which one is better - unreasonable risk, reasonable certainty of no harm - is there a difference?
- **Co-enforcement** - Should states be allowed to enforce?
- **Regulation of articles of commerce** - When should EPA be allowed to regulate chemicals used in articles in commerce?
- **Chemical Prioritization** - Timing of reviews?
- **Fees** - Who pays?
- **Administration principles** - Silence on preemption?

POLITICAL LANDSCAPE - POLITICS AND PROSPECTS

Why TSCA won't pass

1. Senator Boxer is committed to fight the bill
2. Running out of time - the Presidential election season is upon us
3. Need more compromise but any changes to legislation could bust up fragile group of supporters
4. Congress doesn't pass major environmental bills anymore
5. Wait till next Congress - for a Republican President and Republican controlled Congress

POLITICAL LANDSCAPE - POLITICS AND PROSPECTS

Why TSCA will pass

1. New Republican majority in Senate
2. New House Energy and Commerce Committee ranking Democrat
3. Consensus that TSCA is broken and needs repair
4. Strange bedfellows of supporters
5. Clearing the deck for TSCA reform - no competing environmental bills in committee

PUTTING IT ALL TOGETHER

Don't play Russian Roulette

This may be the year TSCA is finally reformed - before the presidential election is front and center

Despite some opposition there is a growing and more vocal bipartisan, bicameral and multi-stakeholder consensus emerging for TSCA reform - even in a polarized Congress

Yes - there are still tough issues that need to be worked out, and some horse trading is likely to occur...

So - If chemical regulation is important to you now is the time to engage Congress. Because - If you don't have a seat at the table you're on the menu.

California Chemical Regulation Issues – Impacting the U.S. Nationwide



Ed Sangster
San Francisco

CALIFORNIA'S ROLE IN THE GLOBAL ECONOMY

- Economic significance of California makes it hard to avoid market
 - Largest gross state product in U.S.
 - Accounts for 12% of U.S. gross domestic product
 - Overtaking Brazil as the world's seventh-largest economy, a year after surpassing Russia and Italy



CALIFORNIA'S ROLE IN THE GLOBAL ECONOMY CONTD.

- California has exploited its economic power to “export” its chemical regulations
- Modern supply and distribution chains make it nearly impossible to design and ship “California-specific” products or labels

PRODUCT LABELING - “PROPOSITION 65”

Overview

- "Clear and reasonable" warning required before “knowing and intentional” “exposure” to chemicals known to State of California to cause cancer, birth defects or reproductive harm
- State now lists 800+ chemicals and substances



PRODUCT LABELING - “PROPOSITION 65” CONTD.

Overview Contd.

- Applies to all businesses in the chain of commerce into California
 - Exception: Companies with fewer than 10 employees
 - Regulatory exception for substances “naturally occurring” in food
- Potential penalties of \$2,500 per day for each violation

PROPOSITION 65 EXCEPTIONS

- For cancer-causing chemicals, exposure poses no significant risk at that level (“NSRL”)
- For reproductive toxins, no observable effect at 1,000 times the exposure
- Regulatory “safe harbor” exposures
 - Safe harbor levels for approximately 300 out of 800 listed chemicals
 - Very low exposures
- If no “safe harbor” threshold, or above safe harbor threshold, companies have burden of proof
 - Very costly and time consuming

PROPOSITION 65 ENFORCEMENT

- Enforced by public prosecutors and private “bounty hunters” who share in any penalties and recover their attorney fees
- 60-Day Notice of Violation
- High cost of litigation and potentially crippling penalties mean that most cases settle

PROPOSED REGULATORY CHANGES

- Overall goal: make warnings more explicit and noticeable
- Changes to wording of “safe harbor” warnings
 - Explicit identification of exposures to 12 chemicals
 - Includes lead, arsenic, DEHP and other Phthalates, and acrylamide
- Change to style and size of “safe harbor” warnings
 - Substantial changes proposed to size, style and placement of safe harbor warnings

PRODUCT CONTENT AND SAFETY - “SAFER CONSUMER PRODUCTS REGULATIONS”

- Preventive approach to keeping dangerous chemicals out of everyday products
- Goal: shift the burden of assessing toxicity from downstream users to upstream manufacturers.
- Will require manufacturers to “systematically evaluate alternative ingredients by requiring that manufacturers ask: ‘is this ingredient necessary, and are there Safer Consumer Products Regulations?’”

SAFER CONSUMER PRODUCTS REGULATIONS - DISTINCTION FROM TSCA

- TSCA program is aimed at *chemicals* management.
 - Not concerned with product safety
- Safer Consumer Products Regulations focus on product safety from the standpoint of public health and the environment.



SAFER CONSUMER PRODUCTS REGULATIONS - INITIAL IMPLEMENTATION

- 3“priority product” categories selected
- Manufacturers required to prepare “alternatives analyses” to determine if safer, nontoxic ingredients will work
- Hundreds of pages of regulations concerning alternatives analysis process
- Broad spectrum of regulatory responses available to regulate after alternatives analyses

SAFER CONSUMER PRODUCTS REGULATIONS - INITIAL IMPLEMENTATION CONTD.

- Program will expand through implementation of 3 year work plan
- Beauty products, building products, furniture, fishing equipment, office products
- Identification of specific products within these categories that will be investigated as potential Priority Products

PRODUCT DISPOSAL

- “Green Chemistry Initiative” focus on life cycle management and waste reduction
- “Safe medicine disposal” ordinances
- Enforcement actions based on returned products



REACH – Overview and Hot Topics



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OVERVIEW

- Ultimate purpose: control and in some cases elimination of hazardous chemicals
- Requires registration of substances
- “One substance, one registration”:
manufacturers and importers of the same substance submit joint registration
- Deadlines for registration (2010, 2013 and 2018) depending on tonnage and hazard profile

SUBSTANCES OF VERY HIGH CONCERN (SVHC)

- REACH aims to ensure that risks from SVHCs are controlled and SVHCs ultimately replaced by suitable alternatives
- SVHCs are substances identified as:
 - Carcinogenic, mutagenic or toxic (for reproduction)
 - Persistent, bio-accumulative and toxic
 - Very persistent and very bio-accumulative
 - Identified from scientific evidence as causing probable equivalent serious effects to human health or the environment
- Procedure involves progression from Candidate List to Annex XIV (authorisation)

HOT TOPIC - AUTHORISATION

- Manufacturers, importers or downstream users must apply for authorization before **using**, or placing on the market for a **use**, any SVHC listed in Annex XIV
- Authorisation granted only if:
 - risk adequately controlled or
 - socio-economic benefits outweigh risk *and* no suitable alternative
- Authorisation is specific to **applicant** and to **use**
- Authorisation required for use after “sunset” date, regardless of quantity used

HOT TOPIC - RESTRICTION

- A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction, shall not be **manufactured, placed on the market or used** unless it complies with the conditions of that restriction
- Substances included in Annex XVII when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market which needs to be addressed on an EU-wide basis
- No tonnage threshold
- May be complete ban or specified uses

HOT TOPIC - INTERMEDIATES

- A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance
- Reduced information requirements if manufactured and used under strictly controlled conditions
- Not subject to authorisation
- ECHA enforcement action

HOT TOPIC – DATA-SHARING

- Information required for registration
- Registrants required to share data
- Data-sharing is either by upfront agreement or by purchase of Letter of Access
- Previous and potential registrants must make “every effort” to ensure that the costs of data-sharing are determined in a “fair, transparent and non-discriminatory way”

DECISION OF ECHA BoA

- Vanadium Consortium cost for Letter of Access:
 - €44,000 base fee
 - 10% annual increase for LoA obtained after 2010
 - €1000 administrative charge
- BoA: any cost-sharing arrangements must ensure that costs are shared fairly amongst all registrants of the same substance
- Additional charge payable only by registrants purchasing LoA after 2010 is de facto discriminatory unless there are legitimate and justifiable reasons for different treatment

DRAFT COST-SHARING REGULATION

- European Commission has proposed an implementing act on data-sharing in REACH
- Additional requirements for transparency, fairness and non-discrimination in cost-sharing
- Industry concerns regarding retroactive effect



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THANK YOU.

For more information, please visit K&L Gates and our Environmental, Land & Natural Resources Practice at <http://www.klgates.com/environmental-land-and-natural-resources-practices/>.

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