SQUIRE PATTON BOGGS

OCTC Ohio Chemistry Technology Council

Chemical Regulatory Developments and "New" TSCA at Two Years Old and Counting

Agenda	
8:30 a.m.	**Registration, Networking and Refreshments**
9:30 a.m.	**Welcome and Introductions** • Karen A. Winters, Partner, Squire Patton Boggs, Environmental, Safety & Health Practice Group Leader (Columbus) • **Jennifer Klein**, President, Ohio Chemistry Technology Council
9:45 a.m.	**Insights and Perspectives on Environmental Policy in the Trump Administration and the Upcoming Mid Term Elections** • Timothy J. Cosgrove, Partner, Squire Patton Boggs (Cleveland)
10:15 a.m.	**Cooperative Federalism: The Changing Roles of States and US EPA** • **Craig W. Butler**, Director, Ohio Environmental Protection Agency
11 a.m.	**Keynote Presentation – US EPA Implementation of the Amended Toxic Substances Control Act** • **Dr. Jeffrey Morris**, Ph.D., Director, Office of Pollution Prevention and Toxics, US Environmental Protection Agency
Noon	**Luncheon**
1:15 p.m.	**Panel Discussion – "Retail" Regulation of Chemical Products: Dealing with Ingredient Bans and Disclosure Requirements** **Moderator:** • W. Caffey Norman, Partner, Squire Patton Boggs (Washington DC) **Panelists:** • **Mary Marrero**, North America Regulatory and Technical Relations Manager, Procter & Gamble • **Christina Shaw Grasseschi**, Legal Manager, Regulatory & Advertising Law, Scotts Miracle-Gro Company • **Joe Yost**, Vice President, Strategic Alliances & Industry Relations, Household & Commercial Products Association
2:30 p.m.	**Coping With California Proposition 65** • Kendra S. Sherman, Partner, Squire Patton Boggs (Columbus)
3 p.m.	**Looking Ahead: An Overview of Upcoming TSCA Deadlines, Reporting Requirements and Challenges to US EPA's TSCA Regulations** • Stephen A. Owens, Partner, Squire Patton Boggs (Phoenix and Washington DC) (former US EPA Assistant Administrator, Office of Chemical Safety & Pollution Prevention) • Allen A. Kacenjar, Partner, Squire Patton Boggs (Cleveland)
3:30 p.m.	**Closing Remarks** Karen A. Winters, Partner, Squire Patton Boggs, Environmental, Safety & Health Practice Group Leader (Columbus)

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Chemical Regulatory Developments and “New” TSCA at Two Years Old and Counting

Tuesday, August 7, 2018
8:30 a.m. – 3:30 p.m.

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Welcome and Introductions

Karen A. Winters, Partner, Squire Patton Boggs, Environmental, Safety & Health, Practice Group Leader

Jennifer Klein, President, Ohio Chemistry Technology Council

OCTC Ohio Chemistry Technology Council

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Insights and Perspectives on Environmental Policy in the Trump Administration and the Upcoming Mid Term Elections

Timothy J. Cosgrove,
Partner,
Squire Patton Boggs

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National & State Elections

- **U.S. Congress**
- **Statehouse**
- **Long-term Political Implications**

2018 Midterm Elections

Results of this year's midterm elections will be enormously important in shaping the American political landscape

- Republican legislative agenda could be dead if either house of Congress flips
- More investigations into Trump's administration would ensue if either house of Congress flips
- Trump would be constrained on judges and nominees if Senate flips
- Huge chunk of 2021 redistricting will be determined by this year's elections

Races

- Entire U.S. House of Representatives
- 1/3 of the U.S. Senate
- 36 Governorships
- State Legislature seats

Competitive U.S. House Seats

There are plenty of vulnerable House seats, and Democrats need to flip only 23 to take back the House. Republican seats in play include those from:

Ohio – 12th District special election, Balderson (R) v. O'Connor (D) & 1st District, Chabot (R) v. Pureval (D)

- California
- New York
- New Jersey
- Pennsylvania
- Virginia
- Oregon

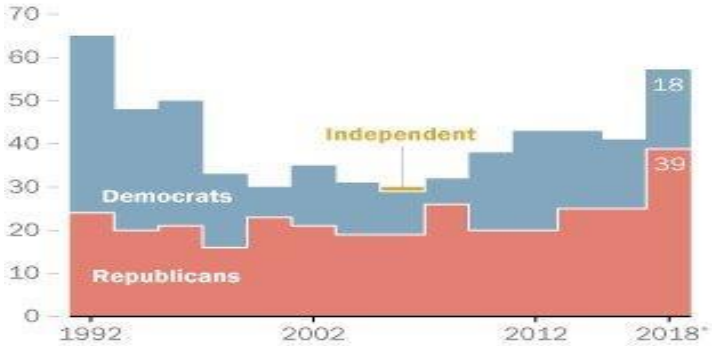
RCP Analysis – 218 seats needed for majority

- 199 Lean Democrat
- 201 Lean Republican
- 35 Toss Up (33 R/2 D)

U.S. House Members Not Seeking Re-Election

More U.S. representatives are not seeking re-election than at any point since 1992

By party affiliation



*Through April 11.
Note: Includes one vacant seat formerly held by a Democrat which will not be filled via special election before November, and one vacant seat formerly held by a Republican for which it's unclear whether there will be a special election before November. Does not include two vacant seats formerly held by Republicans that will be filled via special elections before November.
Source: Pew Research Center analysis.

PEW RESEARCH CENTER

2018 Midterm Elections: Generic Congressional Ballot

With little more than three months left until Election Day, Democrats seem to be strengthening their position to win control of the House

- Both Quinnipiac University and the Kaiser Family Foundation found Democrats with a 12-point lead in the generic congressional ballot – that is well above what political scientists think they need to win back the House (7 points or so)
- Democrats' lead in the generic ballot, according to RealClearPolitics polling average, has quietly doubled (and then some) since the beginning of June, from a mere 3.2 percentage points to a healthy 7.8 points.

(Source: Vox, 2 new polls give Democrats a double-digit lead in 2018 generic ballot. July 25, 2018)

2018 Midterm Elections: Presidential Job Approval

According to RCP Polling Data Average, Trump's job approval rating is 43.1 and disapproval 52.6, a -9.5 spread

- History tells us that the presidents party almost always loses House seats, which has happened in 35 out of the 38 midterm elections (92 percent) since the end of the civil war
- When a president has job-approval ratings of 50 percent or higher, his party tends to keep its losses fairy low
- In 6 of 7 midterm elections since 1966, when presidential approval ratings hovered below 50 percent, his party has lost two dozen or more seats in the House, giving the opposition party a majority the next year

History of Midterm Elections

History tells us that midterm elections are bad for the party that controls the White House. It's a trend that began as early as the Civil War and is firmly established in the era of the modern presidency

1938 – big losses for FDR in the U.S. House over economy and New Deal

1950 – Truman suffers through big GOP night six years into his presidency

1986 – Reagan campaigns for GOP, but voters choose Democrats, giving that party control of the U.S. Senate

1994 – Clinton is beaten in the year of the "Republican Revolution"

1998/2002 – the exceptions (Clinton in 1998 and George W. Bush in 2002)

2006 – Discontent over Iraq war leads to Bush midterm thumping

2010 – Tea Party and a revitalized GOP

(Source: NPR, The Devastating History of Midterm Elections. October 30, 2014)

Competitive U.S. Senate Seats

Democrats have a tall order to take over the Senate. They have to defend 10 seats in states that Trump won and pick up 2 more to gain control. Republican seats in play include those from:

- Nevada – Incumbent Dean Heller (R) v. Rep. Jacky Rosen (D)
- Texas – Incumbent Ted Cruz (R) v. Beto O' Rourke (D)
- Arizona – Martha McSally (R) v. Rep. Kyrsten Sinema (D)
- Tennessee – Rep. Marsha Blackburn (R) v. Former Gov. Phil Bredesen (D)

U.S. Senate members not seeking re-election:

Bob Corker (R- Tennessee)

Jeff Flake (R- Arizona)

Orrin Hatch (R-Utah)

Trump States with Democrats Up for Re-Election

- Montana (Jon Tester D/Matt Rosendale R)
- North Dakota (Heidi Heitkamp D/Kevin Cramer R)
- Missouri (Claire McCaskill D/ Josh Hawley R)
- Indiana (Joe Donnelly D/Mike Braun R)
- Ohio (Sherrod Brown D/Jim Renacci R)
- West Virginia (Joe Manchin D/Patrick Morrisey R)
- Florida (Bill Nelson D/Rick Scott R)
- Wisconsin (*Awaiting Primary Results*)
- Pennsylvania (Bob Casey D/Lou Barletta R)
- Michigan (*Awaiting Primary Results*)

Trends to Watch

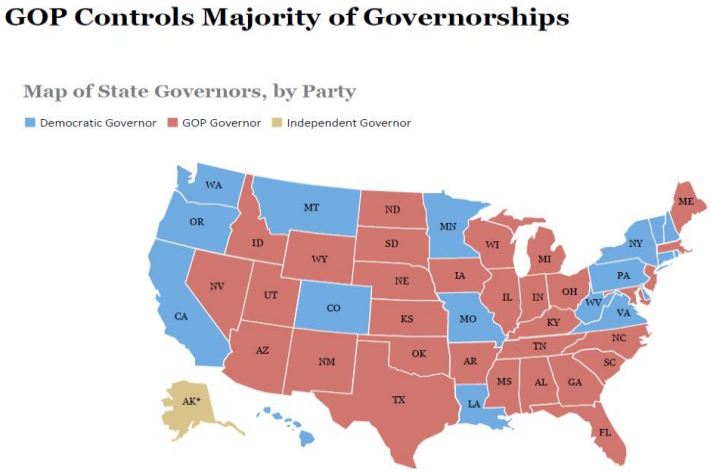
- **Shifting Republican Base**
- **Impact of Women Voters**
- **Direction of Country Outlook**
  - **Right Track 40.6%, Wrong Track 52.3%**

State Races

Currently 33 Republican Governors, 1 Independent and 16 Democrat Governors nationwide

36 Governor's Races

7 toss-ups, all currently held by Republicans



Ohio: Political Landscape Overview

Current Statewide Office Holders

Governor John Kasich (R)

Lt. Governor Mary Taylor (R)

- Attorney General Mike DeWine (R)
- Auditor Dave Yost (R)
- Secretary of State Jon Husted (R)
- Treasurer Josh Mandel (R)

Political Landscape Overview

Ohio House

- 65 Republicans (record majority reached in 2014)
- 34 Democrats
- All **99** seats up for election this fall
- New House Speaker
  - Ryan Smith (R)

Ohio Senate

- 23 Republicans
- 10 Democrats
- 17 of 33 Seats up for election this fall
- Term Limited
  - Manning
  - LaRose
  - Oelslager
  - Skindell

Competitive Statehouse Races

Ohio House

- 55th District
  - Kelly Mencke (D)
  - Gayle Manning (R)
- 89th District
  - Joe Helle (D)
  - Steven Arndt (R)
- 94th District
  - Taylor Sappington (D)
  - Jay Edwards (R)

Ohio Senate

- 13th District
  - Sharon Sweda (D)
  - Nathan Manning (R)
- 27th District
  - Adam Van Ho (D)
  - Kristina Roegner (R)
- 29th District
  - Lauren Friedman (D)
  - Kirk Schuring (R)

Race for Ohio Governor: 2018

Following a crowded primary election, Democrat Richard Cordray and Republican Mike DeWine will face off in November. Polls reflect a close race between the two challengers and top issues important to voters include the economy, health care, education and gun control.

- Republican Ticket: Ohio Attorney General Mike DeWine/Ohio Secretary of State Jon Husted
- Democrat Ticket: Former Executive Director Federal Consumer Financial Protection Bureau Richard Cordray/Former Congresswoman Betty Sutton

Recent polling now views the Ohio gubernatorial contest a “toss-up” after being rated “leans republican”

2018 Statewide Office Races

U.S. Senate

- U.S. Rep. Jim Renacci (R) v. U.S. Senator Sherrod Brown (D)

Ohio Attorney General

- Auditor Dave Yost (R) v. Former U.S. Attorney Steve Dettelbach (D)

Ohio State Auditor

- State Rep. Keith Faber (R) v. Former Congressman Zack Space (D)

Ohio State Treasurer

- State Rep. Robert Sprague (R) v. Rob Richardson (D)

Ohio Secretary of State

- State Sen. Frank LaRose (R) v. State Rep. Kathleen Clyde (D)

Status of Ohio Race

RCP Average

- Cordray + 1.6%
- DeWine 41%

- **Fundraising Numbers**
- **Historical Pattern in “Down Ticket” Races**
- **Kasich Job Approval** – Right Track/Wrong Track

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Cooperative Federalism: The Changing Roles of States and US EPA

Craig W. Butler,
Director,
Ohio Environmental Protection Agency

OCTC
Ohio Chemistry Technology Council

EPA Office of Chemical Safety & Pollution Prevention

Accomplishments and Priorities Under TOXIC SUBSTANCES CONTROL ACT (TSCA)

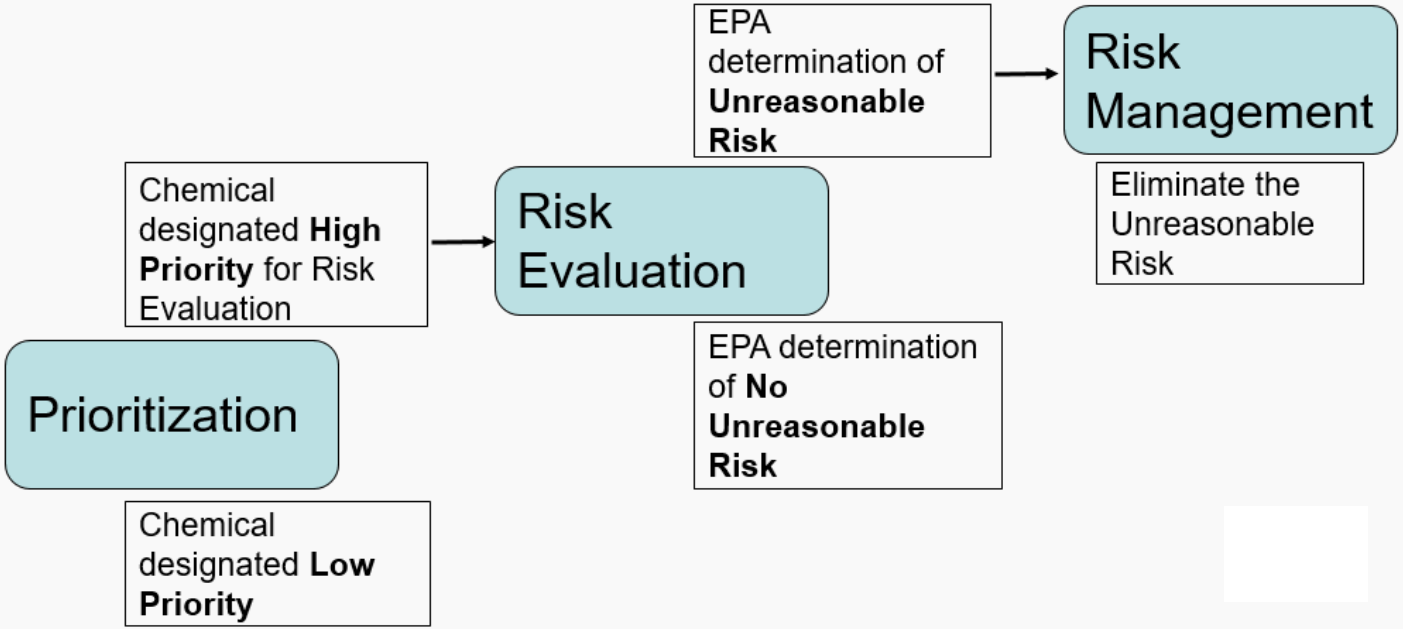
Jeff Morris, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Presentation to the Ohio Chemistry Technology Council
August 7, 2018

TSCA Year 2 Accomplishments

- Asbestos Significant New Use Rule
- Problem Formulations
- Systematic Review
- Mercury Reporting Rule
- Strategy to Reduce Animal Testing
- Transparency and CBI
  - Unique Identifier
  - Generic Name Guidance
  - Expanded Access to CBI Guidance
- Dust-Lead Hazard Standards Proposal

Existing Chemicals Under TSCA



Priorities

- Establishing a Fees Program
- TSCA Inventory Notification (Active-Inactive)
- Completing First 10 Risk Evaluations
- Selecting the Next 40 Chemicals for Prioritization
- Addressing Persistent, Bioaccumulative, and Toxic Chemicals
- Enhancing New Chemicals Review

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Luncheon

Program to resume promptly at 1:15 p.m.

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Panel Discussion

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Panel Discussion

“Retail” Regulation of Chemical Products: Dealing with Ingredient Bans and Disclosure Requirements

- Moderator:
  - **W. Caffey Norman**, Partner, Squire Patton Boggs (Washington DC)

- Panelists:
  - **Joe Yost**, Vice President, Strategic Alliances & Industry Relations, Household & Commercial Products Association
  - **Mary Marrero**, North America Regulatory and Technical Relations Manager, Procter & Gamble
  - **Christina Shaw Grasseschi**, Legal Manager, Regulatory & Advertising Law, Scotts Miracle-Gro Company

Case Study/Methylene Chloride-Based Paint Strippers/Current Restrictions

- In 1987, the CPSC issued a Statement of Interpretation and Enforcement Policy regarding the labeling of house-hold products containing methylene chloride for chronic hazard.
- With the support of industry, an updated policy with a stronger label addressing the asphyxiation risk was issued by the CPSC in March 2018.
- In 1997, OSHA adopted a PEL of 25 parts per million for methylene chloride in the workplace.

Cautionary Language Approved in 2018

Front (Primary Display)

WARNING: Contains Methylene Chloride. **INHALATION OF VAPOR CAN KILL YOU. DO NOT USE IN ENCLOSED AREAS** such as basements, bathrooms or closets. **SYMPTOMS MAY NOT BE NOTICEABLE.** Avoid contact with eyes or skin, as severe irritation can occur. Methylene Chloride may cause cancer. The risk to your health depends on the level and duration of exposure.

Top of Back Panel

California Action

- In March 2014, the California Department of Toxic Substances Control (DTSC) identified paint strippers containing methylene chloride as one of three priority products under its Safer Consumer Products regulation.
- DTSC has issued guidance for alternatives analyses but rulemaking on methylene chloride has not commenced.

Methylene Chloride-Based Paint Strippers under TSCA

- On January 19, 2017 EPA proposed a ban under TSCA § 6 on:
  - Manufacture/sale/use of methylene chloride for paint removal except for commercial furniture stripping or for certain components of military aviation and vessels;
  - Sale of methylene chloride for paint removal in containers with a volume less than 55 gallons.
- At year-end, EPA placed the proposed ban on a “long term action” list.
- In early May 2018, parents of young men who had died using DCM-based paint strippers visited Congressional offices and met with Administrator Pruitt.
- Shortly thereafter, on May 10, EPA announced that it would be moving forward to adopt a final rule on these products and would send it to OMB “shortly.”
- EPA’s problem formulation document for methylene chloride, issued in early June, expressly excludes the paint removal use.

Retailer Action

- On May 29, 2018, following EPA's press release and in the face of a threatened demonstration at its annual meeting, Lowe's announced that by the end of 2018 it would no longer sell paint removal products formulated with methylene chloride or NMP.
- On June 15, as part of their Mind the Store campaign, NRDC and Safer Chemicals, Healthy Families sent aggressive letters to major retailers highlighting the reputational, litigation, and regulatory risk of selling these products and urging them to follow Lowe's lead.
- On June 18/19, Sherwin-Williams and Home Depot made similar announcements.

Panel Discussion

“Retail” Regulation of Chemical Products: Dealing with Ingredient Bans and Disclosure Requirements

Joe Yost,

Vice President, Strategic Alliances & Industry Relations,

Household & Commercial Products Association

Panel Discussion

What Is Driving Retailers to Develop Chemical Management Policies?

- Environmental Non-governmental Organizations (NGOs)
  - Environmental Defense Fund (EDF) Partnership with Walmart – since 2005
    - Eliminate “chemicals of concern” from everyday products
    - Create transparency for consumer products
  - Mind the Store - Safer Chemicals Healthy Families
    - 2017 Annual Report Card graded 30 major U.S. retailers’ chemical management policies for consumer products https://retailerreportcard.com/retailers/
- State Legislation & Regulation
  - California Cleaning Products Right to Know Act (SB 258)
  - New York State Department of Environmental Conservation (NYSDEC)
    - Household Cleansing Product Information Disclosure Program

Panel Discussion

Environmental Defense Fund Partnership with Walmart

- **2005** - Walmart consulted with EDF on corporate sustainability strategy
- **2007** - EDF established a permanent office in Bentonville, Arkansas, adjacent to Walmart corporate headquarters
- **2007** - Walmart provided seed money to create The Sustainability Consortium (TSC)
- **2009** - TSC is established - comprised of corporations, non-profits & academic institutions from around the world to increase sustainability in consumer product supply chains
- **2013** - Walmart issued its policy on chemical ingredients in home & personal care products
  - Require suppliers to provide ingredient information *via* The WERCS platform
- **2014** - Walmart gave notice to its consumer product suppliers requiring the phase out of certain “chemicals of concern”
- **2018** – Walmart required suppliers to begin on-pack label disclosure for “priority chemicals”

Panel Discussion

Safer Chemicals Healthy Families - Mind the Store Campaign

Report Card Ranking 30 Top Retailers on Safer Chemical Policies

9 Primary Metrics:

- Policy
- Oversight
- Accountability
- Disclosure
- Action
- Safer Alternatives
- Transparency
- Chemical Footprint
- Third-party Standards

Panel Discussion

California Cleaning Products Right to Know Act (SB 258) - overview

- Took effect January 2018
- Applies to manufacturers of “designated products” sold in California – the label will determine how a product is categorized:
  - Air care products
  - Automotive products
  - General cleaning products
  - Polish or floor maintenance products
- Does not apply to:
  - Food, drugs and cosmetics
  - Industrial products
- Provides exemptions for confidential business information (CBI)

Panel Discussion

California Cleaning Products Right to Know Act (SB 258) - overview

- Requires On-line Disclosure by January 1, 2020
  - List “intentionally added” ingredients
  - List all fragrance allergens at a concentration at or above 0.01% (100 parts per million)
  - Must include the Chemical Abstracts Service (CAS) chemical identification number for all listed chemicals
  - FIFRA products that meet the definition of “designated product” must provide on-line disclosure
- Requires On-Label Disclosure by January 1, 2021
  - FIFRA products are NOT subject to on-label disclosure requirements

Panel Discussion

NYSDEC Household Cleansing Product Information Disclosure Program - overview

- June 2018 – NYSDEC issued final Policy on Household Cleansing Product Information Disclosure
- Manufacturers must submit Disclosure Certification Form signed by a senior management official
- July 1, 2019 – manufacturers must post online disclosure:
  - Intentionally added ingredients other than fragrance
  - Nonfunctional ingredients present above trace quantities
  - Small businesses must post information by July 1, 2020
- July 1, 2020 – manufacturers must post online disclosure:
  - Fragrance Ingredients
  - Nonfunctional byproducts at or above 100 parts per million
- July 1, 2023 – manufacturers must post online disclosure:
  - Nonfunctional byproducts
  - Nonfunctional contaminants
- Manufacturers must update disclosure each time products ingredients are changed

Panel Discussion

State Ingredient Disclosure Laws Create Complications for Commercial Commerce

- California Law and New York Program impose different disclosure requirements
  - New York will require disclosure of byproducts and contaminants
  - Scope of the New York Disclosure Program may be expanded in the future
- Other states may enact similar (but different) disclosure laws in the future
  - Programs seek to achieve a similar goal – disclosure. But the disclosure requirements may differ considerably on a state-by-state basis
  - Aligning these differing state disclosure requirements will become more difficult

Panel Discussion

HCPA Focus on Retail Engagement

- HCPA formed the Strategic Alliances & Industry Relations Department
  - Expand and strengthen HCPA's relationships with NGOs, retailers, industry and all levels of government
  - Increase the industry's sustainability efforts
- HCPA formed the Retail Engagement Work Group (REWG)
  - Maintain ongoing dialogues with retailers about current and planned chemical management programs
  - Advocate harmonization of retailers' ingredient disclosure and sustainability requirements

Panel Discussion

HCPA REWG Collaboration with Retailers on Label Requirements

- Worked cooperatively with Walmart to provide recommendations for implementing Walmart's January 2018 on pack label disclosure requirement for "priority chemicals"
  - Walmart modified its existing policy to include several of the REWG's key recommendations
- Target recently asked for REWG's feedback on Target's draft chemical safety implementation plan
- Lowe's banned the sale of paint strippers containing methylene chloride and NMP
  - HCPA met with Lowe's senior managers to discuss the development of Lowe's risk-based chemical management policy

Panel Discussion

Retailers Use UL-WERCSmart for Regulatory Compliance

- WERCSmart is an electronic data portal
- 11,000+ Product manufacturers provide information about chemical ingredients in their products
- 40+ Retailers use WERCSmart data to ensure compliance with federal and state environmental regulations
- Product formulation information & other CBI is never disclosed to retailers

Retailers Use UL-WERCSmart for Chemical Policies

- Retailers are requiring suppliers to use WERCSmart's new data tiers to provide more information about product ingredients
  - Tier 1 - Regulatory Support
  - Tier 2 - Chemical Program Support
  - Tier 3 - Supplemental Report Support
  - Tier 4 - Public Disclosure Options

Panel Discussion

UL-Wercs Advisory Council

- HCPA and 5 other trade associations' CEOs contacted UL CEO and recommended the formation of an advisory council that includes retailers, product manufacturers and suppliers
- UL-WERCS formed an Advisory Council in January 2018
  - 4 major retailers
  - 8 product manufacturers and suppliers
  - HCPA
- Product manufacturers work in cooperative partnership with retailers and UL-WERCS to:
  - Increase efficiency and accuracy of the data submission process
  - Reduce costs for retailers, product manufacturers and UL

Panel Discussion

HCPA Is Building Stronger Relationships with Retailers

HCPA's Annual Meeting in December 2017 featured a panel discussion of the relationships between product manufacturers and retailers

- Tom Flicker, Principal, Sustainable Product Development, Target
- Ashley C. Hall, Sustainability, Walmart
- Kieran Callahan, Supply Chain and Sustainability, UL-Wercs
- Boma Brown-West, Environmental Defense Fund (EDF)
- Monica Becker, Co-Director and Collaborative Innovation Project Lead, Green Chemistry and Commerce Council (GC3)

Panel Discussion

“Retail” Regulation of Chemical Products: Dealing with Ingredient Bans and Disclosure Requirements

Mary Marrero,

North America Regulatory and Technical Relations Manager,

Procter & Gamble

Retailer Chemical Regulatory Developments

The Procter & Gamble Company

- P&G serves nearly 5 billion consumers around the globe
- $2 billion annual investment in innovation
- Global Headquarters: Cincinnati, Ohio

How we started down this path…

- **Example** of retailer use of information delivered. Retailer scans product UPC to determine appropriate Haz Waste bucket. Ensures proper disposal of product.

Hazardous Waste

- **One option -- Bucket system**
- **Bucket colors identify the hazardous waste properties**
  (e.g., red for flammables)

Retailer requirements continue to increase…

- Regulatory Compliance
- Retailer Chemical Policies
  - Chemical lists
  - Greater transparency
  - Elimination of chemicals
- Marketing Programs for Consumers
- NGO Influences

Retailer Chemical Policies

Panel Discussion

“Retail” Regulation of Chemical Products: Dealing with Ingredient Bans and Disclosure Requirements

Christina Shaw Grasseschi,

Legal Manager, Regulatory & Advertising Law,

Scotts Miracle-Gro Company

Retailer Reaction to Customer Base

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HUFFPOST

ENVIRONMENT 04/09/2015 02:38 pm ET | Updated Jun 09, 2015

960

Lowe's To Stop Selling Neonicotinoid Pesticides That May Be Harmful To Bees

REUTERS

CHICAGO (Reuters) - Home improvement chain Lowe's Cos Inc will stop selling a type of pesticide suspected of causing a decline in honeybee populations needed to pollinate key American crops, following a few U.S. retailers who have taken similar steps last year.

The class of pesticides known as neonicotinoids, or neonics, are sold by agrichemical companies to boost yields of staple crops but are also used widely on annual and

45

GREENHOUSE GROWER

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ENVIRONMENT JUNE 25, 2014 / 3:20 PM / 4 YEARS AGO

U.S. retailers look to limit pesticides to help honeybees

Carey Gillam 3 MIN READ

(Reuters) - Home Depot and other U.S. companies are working to eliminate or limit

Organic authority SHOP FOODIE BUZZ KITCHEN + RECIPES NUTRITION + WELLNESS LIVE + GROW GUIDES

CHEW NEWS

Aldi Bans 8 Pesticides Including 3 Neonicotinoids from U.S. Stores

AUGUST 3, 2016 by EMILY MONACO

The Home Depot Says No To Neonics

By Laura Drotleff | December 29, 2015 SHARE:

The Home Depot plans to phase out neonicotinoids by 2018, according to a recent statement on the company's website. The large home improvement retailer stated that its live goods suppliers have reduced the number of plants that they treat with neonicotinoids, and now more than 80% of all flowering plants sold at The Home Depot are not treated with neonicotinoids. The retailer said it will continue this decrease unless:

1. Treatment is required by state or federal regulation, or
2. Undisputed science proves that the use of neonicotinoids on live goods does not have a lethal or sub-lethal effect on pollinators

biological products. expert solutions.
CLICK HERE TO LEARN MORE
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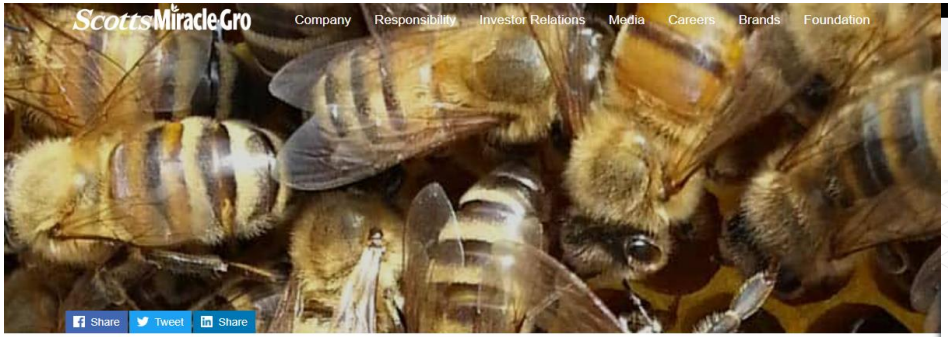
SMG Reaction to Customer Base



Ortho plans to remove Neonics

We're doing what we do best – listening to our consumers and making sure our products fit their needs.

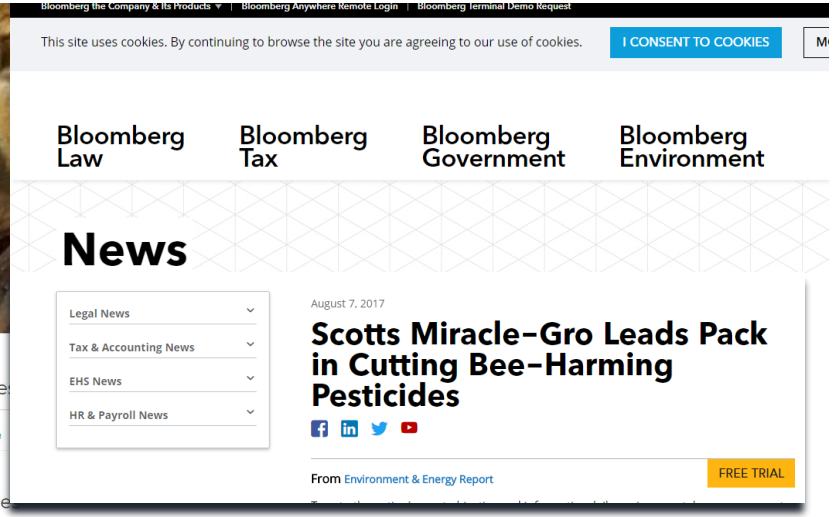
Today Ortho announced that they will immediately begin to transition away from the use of neonicotinoid-based pesticides for outdoor use. Beginning this spring, Ortho will be offering additional non-neonic based solutions. The specific ingredients that will be eliminated in 2016-17 include: Imidacloprid, Clothianadin and Dinotefruan. We expect the full transition to be completed by 2021.

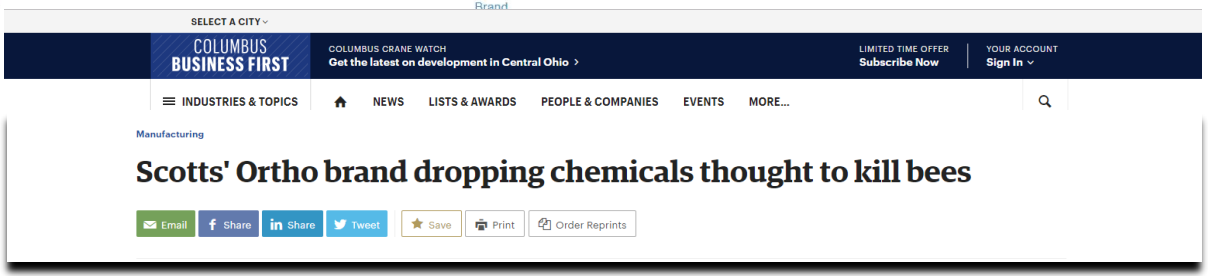
Resource

Press Release

Categorie

Brand





SMG Reaction to Customer Base

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Bee Culture

The Magazine of American Beekeeping

BEEKEEPING / LIFE / SCIENCE / RESOURCES / OPINIONS / CATCH THE BUZZ

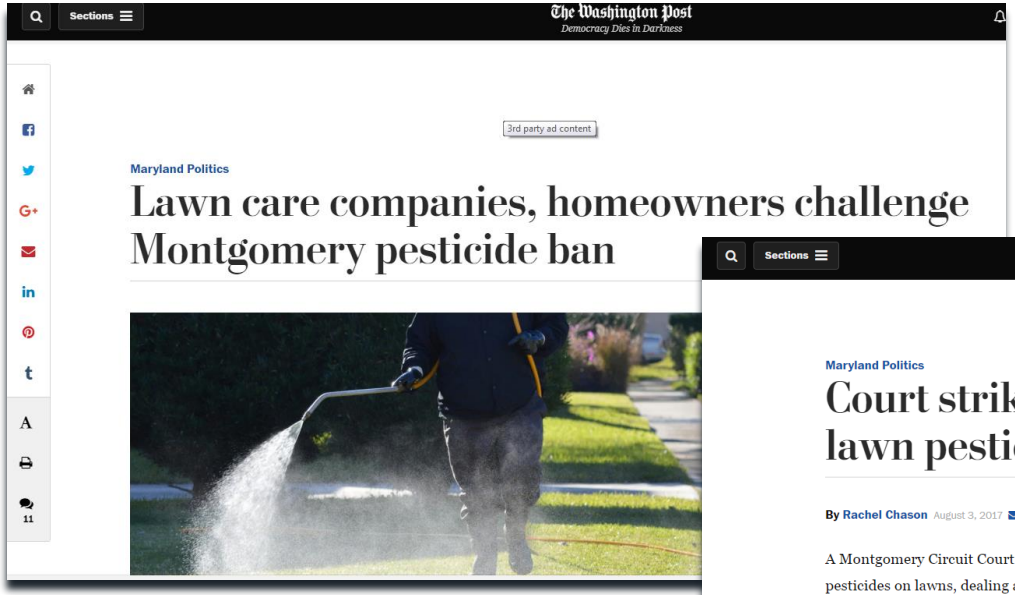
APRIL 26, 2016

CATCH THE BUZZ – ORTHO BRAND ANNOUNCES PLAN TO ELIMINATE NEONICS FROM ALL ITS OUTDOOR PRODUCTS; PARTNERSHIP WITH THE POLLINATOR STEWARDSHIP COUNCIL TO FOCUS ON CONSUMER EDUCATION

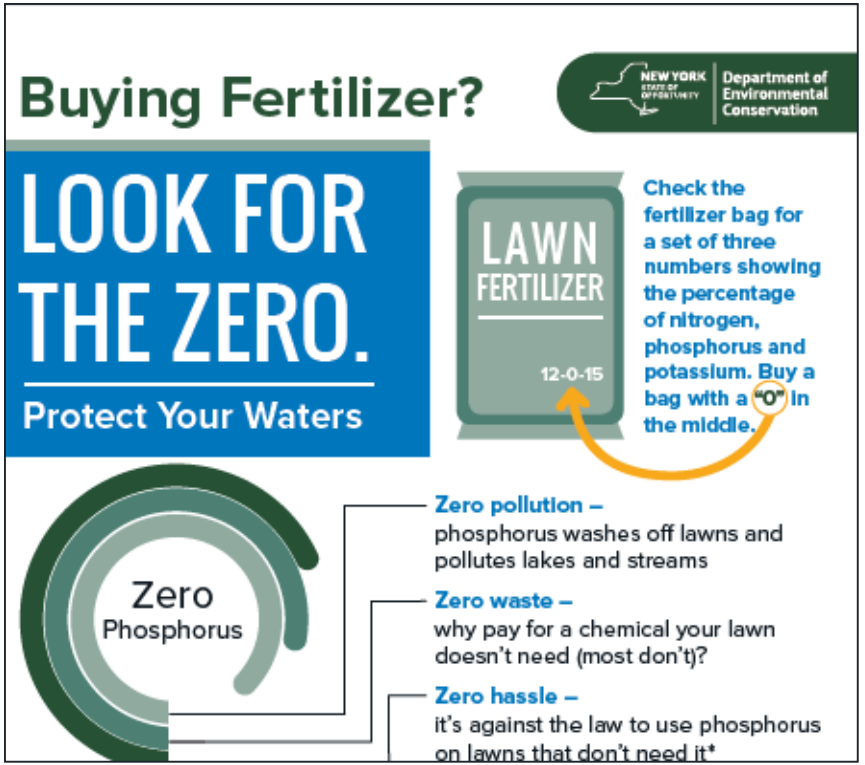
PROTECT POLLINATORS:

BEE RESPONSIBLE

Local Ordinances



State Action



SQUIRE PATTON BOGGS

Coping with California Proposition 65

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Ohio Chemistry Technology Council

Overview

- Background on Proposition 65
- Key Terms in the Statutory Prohibition Language
- What Chemicals Are on the List?
- Do I Need to Label my Product?
- Prosecution of Prop 65 Claims
- Potential Liabilities
- Clear and Reasonable Warning Amendments
- Recent Compliance Questions
- Protection from Prop 65 Liabilities
- Other Tools We Use to Assist

Background on Prop 65

- Officially known as the **Safe Drinking Water and Toxic Enforcement Act of 1986**

  - Enacted as a ballot initiative in the State of California in November 1986. Goal to protect the State's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm
  - Implementing Regulations: CA Code of Regulations, Title 27, Division 4, Sections 25102 through 27001 by CA EPA Office of Environmental Health Hazard Assessment ("OEHHA")
  - Enforcement Statutes: CA Health & Safety Code, Sections 25249.5 through 25249.13

- "*No person in the course of doing business shall **knowingly and intentionally expose** any individual to a **chemical known to the state to cause cancer or reproductive toxicity** **without first giving clear and reasonable warning** to such individual . . .*" CA HSC §25249.6

Key Terms

"No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . ." CA HSC § 25249.6

- Applies to businesses with 10 or more employees
- Applies to all businesses in the chain of commerce (manufacturers, distributors, packagers, importers, suppliers and retailers)
- Applies to out-of-state companies selling or distributing products in California
- "Knowingly and intentionally" (but "actual knowledge" for retailers – heightened standard)
- "Expose"
- Chemicals known to cause cancer or reproductive toxicity
- Without first giving a "clear and reasonable warning"
  Clear and Reasonable Warning Regulations (CA Code of Regulations § 25601-25605.2)

What Chemicals Are On The List?

- **900+ listed chemicals**
- Carcinogens and Reproductive/Developmental Toxins
- Prop 65 requires the State to maintain and update its list of chemicals at least once per year. 12 month grace period of newly listed chemicals. Chemicals may be delisted (rarely).
- Chemicals that most often appear in recent Prop 65 NOVs or lawsuits:
    - **DEHP or phthalates such as DINP and DBP** (plasticizers, vinyl handles, fashion accessories)
    - **1,4-dioxane** (shampoo, hair products)
    - **Diethanolamine** (scented body washes, suncreens)
    - **Lead and lead compounds** (including lead in brass parts)
    - **Cadmium**
    - **Wood dust**

Do I Need to Label My Product?

- **Prop 65 does *not* address *whether* a warning is required.**
- Instead, **Prop 65 describes *how to provide a warning*** once a business had made a determination that a warning is necessary.
- You do not need to label your product if it does not contain a listed chemical, OR if the listed chemicals in your product create such a small amount of exposure to the consumer to fall into the “safe harbor” provisions of Prop 65.
    - No Significant Risk Levels
- **Prop 65 does not require that a business test its products.** For most businesses, it is impossible to know if their products contain listed chemicals and at what exposure amounts without laboratory testing and/or toxicology reports.

Prosecution of Prop 65 Claims

- **Prop 65 cases are frequently enforced by private citizen Plaintiffs**
  - "Bounty hunter" provision allows private parties to bring enforcement actions AND collect their attorneys' fees.
  - **60-Day Notice Letter** (Identification of prosecutor/attorney and Certificate of Merit)
  - CA Attorney General or Local District Attorney may also prosecute (more rare)
- **<u>Very</u> low evidentiary burden for Plaintiffs**
  - Plaintiff must only allege a violation and make a prima facie case of "exposure" to a listed chemical.
  - Plaintiff is not required to test a product but must have "facts, studies or other data"
- **Burden shifts to Defendant business** to demonstrate the warning is provided or the risk of exposure meets applicable criteria
  - Carcinogens: One excess case of cancer in an exposed population of 100,000 assuming lifetime exposure at the level in question (10^{-5})
  - Reproductive/developmental toxicants – $1/1000^{th}$ of the No Observable Effect Level (NOEL)

Potential Liabilities

- Potential liabilities and costs of defending/responding to an alleged Prop 65 violation can be significant
- **Civil Penalties ($2500 per day per violation)**
  - 25% to the prosecutor (citizen plaintiff or regulated entity)
  - Each unwarned exposure = one violation
  - Plaintiffs can allege over $1M in fines
  - Average settlement cost $100,000
- **Attorneys' fees**
- **Injunctive relief**
  - Add warnings to your products
  - Reformulation of products

Millions in Private Settlements Every Year	
2017:	$25,767,500
2016:	$30,150,111
2015:	$17,828,941
2014:	$21,047,746
2013:	$16,812,396
2012:	$20,435,722
2011:	$15,891,728
2010:	$13,620,981
2009:	$14,608,177
2008:	$17,804,104

Responding to a Proposition 65 Notice and Lawsuit

- Before a lawsuit can be filed, a plaintiff must provide a business with a 60-day notice of their intent to sue.
- Effect of the notice is to shift the burden to the business to demonstrate the notice and subsequent lawsuit is unfounded.

- Most cases are resolved through negotiated settlements due to the significant cost of litigation.
- 60-Day Notices, NOVs, settlements, penalties, attorney fee awards are all publicly availably at https://oag.ca.gov/prop65
- Updated with near real-time information
- Extremely helpful for comparison

Clear and Reasonable Warning Amendments

- Prop 65's "clear and reasonable" warning requirements were amended in late 2015 and adopted by OEHHA in August 2016
- The newly-amended "clear and reasonable" Prop 65 warning looks like this:

> ⚠ **WARNING**: This product can expose you to chemicals including [name one or more listed chemicals] which [is/are] known to the State of California to cause cancer and [name one or more listed chemicals] which [is/are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

- The effective date of the amended Prop 65 "clear and reasonable" warning amendments is **August 30, 2018.**
- Companies may comply with the amended laws prior to the effective date

Clear and Reasonable Warning Amendments

- **Definitions and Responsibilities** (applies to all warnings)
- **Warnings – Methods and Content** ("safe harbor" provisions)
- **Consumer Products Exposure Warnings**
- **Environmental Exposure Warnings & Occupational Exposure Warnings**
- **Specified Circumstances for Specific Products, Chemicals and Area Exposure Warnings** (e.g., amusement parks, smoking areas, food and beverage products, etc.)

"Safe Harbor" Provisions – non-mandatory method and content requirements that establishes what is a "clear and reasonable" warning

- Provides a "safe harbor" against enforcement actions
- Businesses can choose to use other warning methods and content but must be prepared to defend a NOV or lawsuit

New Safe Harbor Warning

Current Safe Harbor	New Safe Harbor
"This product contains..."	"This product can expose you to..."
No requirement to specify the chemical for which the warning is being provided.	Must specify at least one chemical for which the warning is being provided. If warning for both carcinogenicity and reproductive toxicity, must specify at least one of each.
No requirement to translate warnings.	Where a consumer product sign, label, or shelf tag used to provide a warning includes consumer information in a language other than English, the warning must also be provided in that language.
No requirement to specify a URL.	"For more information go to www.P65Warnings.ca.gov."
No requirement to include a pictogram.	 or 

Other Changes in the New Clear and Reasonable Warning Amendments

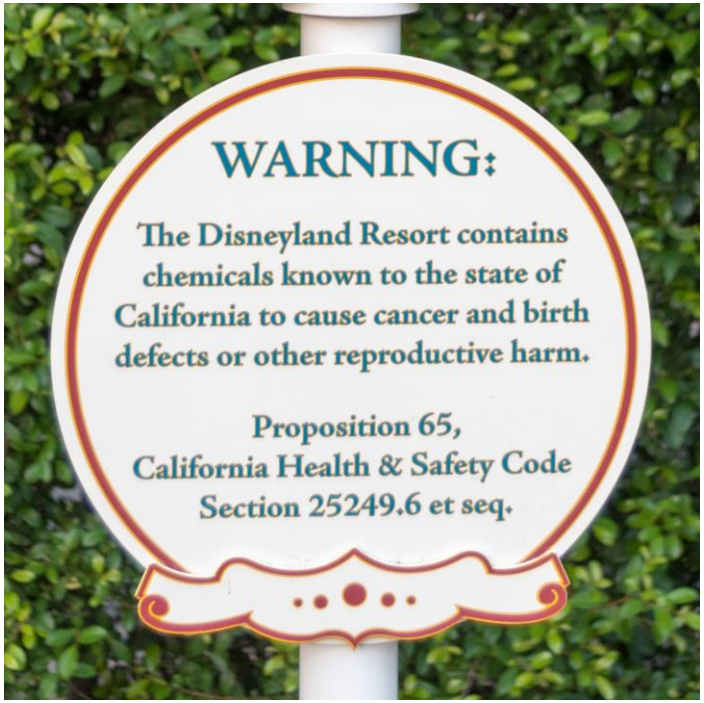
- New warning text and design
- New requirements on “methods of transmission”
  - Location of warning
  - Electronic warnings
  - Short form warnings
  - Internet warnings
  - Catalog warnings
  - Foreign language warnings
- Shifting responsibility primarily to the manufacturer/distributor
  - Retailer only responsible if “actual knowledge”

Coffee Requires a Prop 65 Warning But Monsanto's Round-Up Does Not?

- *Nat'l Assn of Wheat Growers, et al. v. Zeise, et al.*
  - February 26, 2018 decision by US District Judge Shubb that Monsanto was not required to warn for the herbicide glyphosate in its RoundUp products
  - Insufficient evidence that glysophate causes cancer
  - Monsanto avoided civil penalties, paying plaintiffs attorneys fees and injunctive relief
- *Council for Education, et al. v. Starbucks Corp., et al.*
  - March 28, 2018 decision by CA Judge Berle that coffee requires a cancer warning
  - Chemical acrylamide which occurs during the roasting process must be removed from the coffee making process or Prop 65 warning is required.

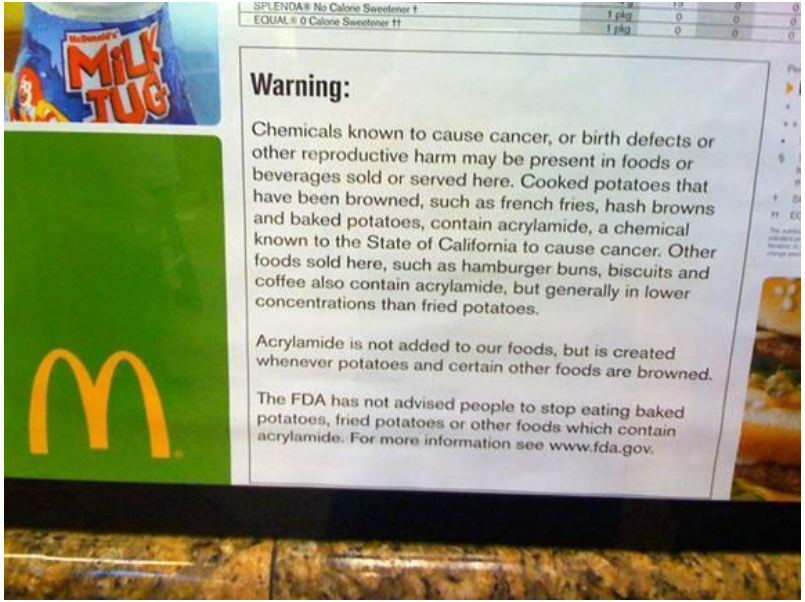
Recent Compliance Questions

- My products are shipped in bulk and sold separately by the retailer, how do I label them?
- Is a label sufficient if I include it in the product manual but not on the product itself?
- Can I supply the Prop 65 warning in the register receipt or invoice with the product after the sale?
- What is the proper font size for signs warning my employees for occupational exposure?



More Compliance Questions

- Do I need to include the warning in languages other than English?
- My competitors are not including a warning on their products, so do I need to?
- What are the requirements for Internet sales?
- What if my products are displayed in a showroom but are not sold to customers there?
- What shelf tags and signs do I provide to the retailer and how often do I have to verify the retailer received the warning?

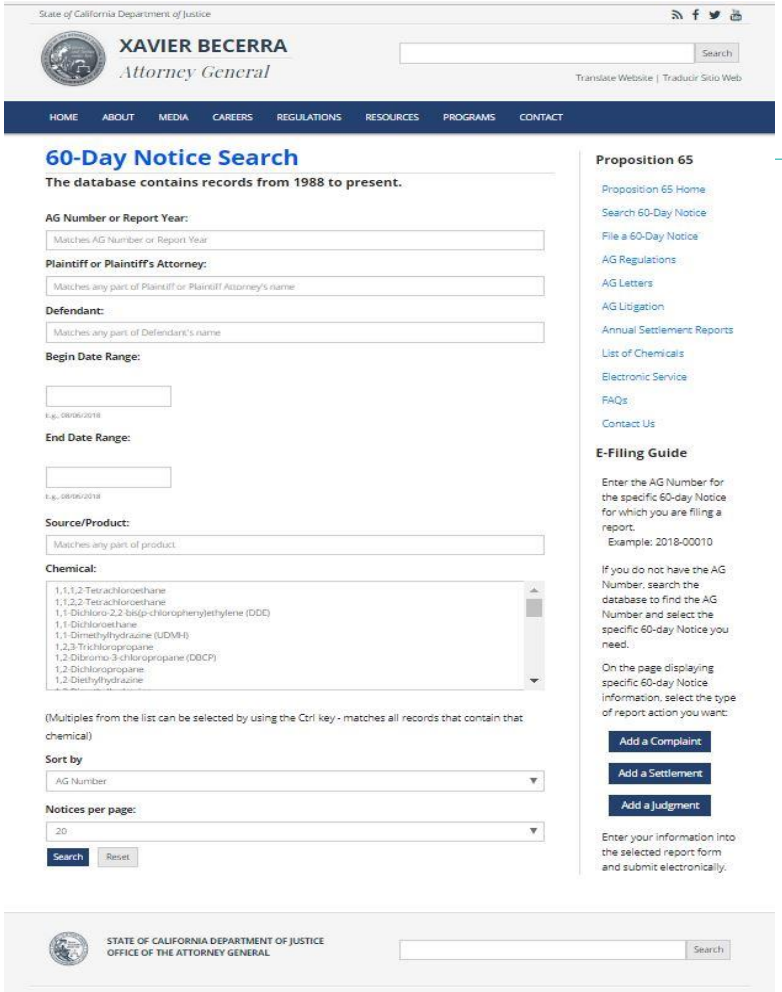


Protection from Prop 65 Liabilities

- Product Testing
- Preemptive Warnings
- Contracts (reps, warranties, and indemnities)
- Verification from upstream suppliers/sellers' compliance
- Audits of products
- Communicate with employees on new requirements
- Maintain proper records
- Insurance

Other Tools We Use to Assist our Clients

- Analyze if similar products have been the subject of Notices of Violations
- Analyze if competitors have been sued
- Focus on chemicals that are more routinely the subject of Notices of Violations
- Prepare compliance programs and product audits
- Verify records maintained
- Review OEHHA Response to Comments
- Compile current information on plaintiffs, attorneys and settlements



https://oag.ca.gov/prop65/60-day-notice-search

Questions?


WARNING:
This product contains chemicals known to the State of California to cause cancer, and birth defects or other reproductive harm. Wash hands after handling.
KISS the Cook

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An Overview of Upcoming TSCA Deadlines, Reporting Requirements and Challenges to US EPA's TSCA Regulations

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Upcoming Key TSCA Deadlines & Events

- August 14, 2018: TSCA Nanomaterials Reporting Deadline
- August 16, 2018: Deadline for comments on problem formulations for the "first ten" TSCA risk evaluations
  - Asbestos; 1-Bromopropane; Carbon Tetrachloride; 1, 4 Dioxane; Cyclic Aliphatic Bromide Cluster (HBCD); Methylene Chloride (MC); N-Methylpyrolidone (NMP); Perchloroethylene; Pigment Violet 29; Trichloroethylene (TCE).
- October 1, 2018: Proposed date for TSCA fees to begin to be incurred
- October 5, 2018: Deadline for TSCA Inventory Reset reporting by processors
- December 2018: EPA to initiate prioritization on 40 substances (20 high-priority candidates & 20 low-priority)
- November 2018: EPA to publish initial reset TSCA Inventory
  - (including substances "identified" for designation as inactive)

Upcoming Key TSCA Deadlines & Events

- February 2019: EPA to publish final reset TSCA Inventory
  - (with substances formally "designated as inactive)(90 days after initial reset Inventory)
- February 2019: "Prospective" reporting begins for TSCA Inventory reset (to redesignate inactive substances as active)
- Early-Mid 2019: EPA to release drafts of the "first ten" TSCA risk evaluations
- June 22, 2019: Deadline for EPA to propose TSCA § 6 rules on 5 PBTs
  - Decabromodiphenyl ethers (DecaBDE); Hexachlorobutadiene (HCBD); Pentachlorothiophenol (PCTP); Tris(4-isopropylphenyl) phosphate; 2,4,6-Tris(tert-butyl) phenol
- July 1, 2019: Deadline for reporting under TSCA mercury rule
- December 2019: EPA must finalize the "first ten" risk evaluations
- December 22, 2019: Deadline for EPA to initiate risk evaluations on at least 20 high priority substances (and designate 20 substances as low priority)

Upcoming Key TSCA Deadlines & Events

- Sometime in 2018 or 2019: EPA will initiate manufacturer-requested risk evaluations on two ethanone substances
  - Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)
  - Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)
- Sometime in 2018 or 2019: EPA will finalize § 6 rule on Methylene Chloride
- Sometime in 2018 or 2019: EPA will finalize TSCA fee rule
- February 2020: EPA must promulgate a rule for reviewing chemical identity CBI claims for active substances on the reset TSCA Inventory
  - (Rule due within one year after EPA issues final reset TSCA Inventory)
- June 2020: Deadline for EPA scoping documents for 20 new risk evaluations
- December 22, 2020: Deadline for EPA to issue final § 6 rules on the 5 PBTs

Inventory Reset Rule (EDF v. EPA, D.C. Cir. No. 17-1201)

- **Inventory Reset Rule**
  - Finalized in August 2017 to divide the TSCA Inventory into “active” and “inactive” chemicals
- **Primary Issues Raised by Petitioner**
  - Confidentiality
    - The rule allows manufacturers and processors to improperly assert “new claims” based upon the existing claims of others.
    - The final rule’s confidentiality requirements are less burdensome than TSCA requires.
  - Final rule fails to provide the public with information required by TSCA § 8
    - For example, a unique identifier for chemicals on the confidential portion of the Inventory.
  - Chemical substances solely for export must be subject to TSCA § 8
- **Agency Position**
  - No standing – No injury
  - Plain language lets any manufacturer/processor maintain confidentiality claims
  - Public information requirements unrelated
  - Export-only manufacturer exemption was reasonable
- **Status – Fully briefed, argument being scheduled.**

New Chemicals Decision-Making Framework (NRDC v. EPA, 2nd Cir. No. 18-25)

- **"Rule" - New Chemicals Decision-Making Framework**
  - Published November 2017 to explain EPA's approach for decision-making on new chemical notice submissions
- **Primary Issues Raised by Petitioner**
  - The Framework fails to provide the comprehensive review TSCA requires
    - EPA must consider both potential and intended conditions of use.
  - EPA must issue an order, not a SNUR, to address concerns with reasonably foreseen conditions of use
  - The Agency disregarded mandatory notice and comment procedures
- **Agency Position**
  - No standing – No injury
  - The Framework cannot be appealed because it is not a final rule
  - The Framework is consistent with TSCA (Agency deference)
- **Status: Briefing nearing completion. Oral argument - likely late 2018**

Risk Prioritization and Risk Evaluation Rules (NRDC v. EPA, 9th Circuit No. 17-73290)

- **Background**
  - Suits Originated in the Ninth and Fourth Circuits, consolidated in the 9th Circuit
- **Primary Issues Raised by Petitioners**
  - Risk evaluations must consider all conditions of use
    - The final rule permits EPA to determine which conditions of use to analyze. Instead, EPA must analyze all contributing hazards and exposures of a chemical.
  - Use by use approach for risk determinations is improper
    - Such piecemeal analysis may overlook cumulative impacts.
  - EPA unlawfully omitted certain uses and disposals from conditions of use
    - A chemical's "conditions of use" include ongoing and future use and disposal of the chemical.
  - Rules contradict EPA's duty to consider all reasonably available information
    - The Final Rule penalizes incomplete submissions and permits manufacturers to withhold information about a chemical substance.
- **Status: Mediation Recently Failed, EPA's Brief Due August 6, 2018.**

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Closing Remarks

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Global Coverage

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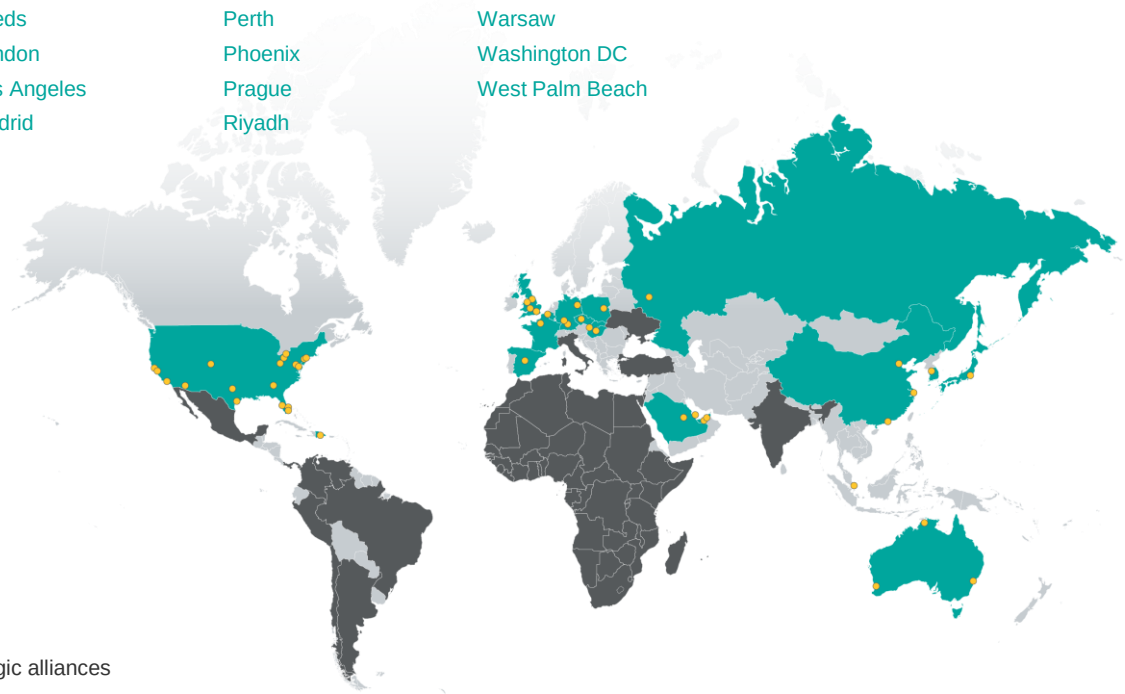

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Office locations

Regional desks and strategic alliances

PROPOSITION 65[1]

CLEAR AND REASONABLE WARNINGS

QUESTIONS AND ANSWERS FOR BUSINESSES

Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

Revised July 2018

Contents

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, codified at Health and Safety Code section 25249.5 *et seq.* Hereafter referred to as "Proposition 65" or "the Act".

Modified Article 6 Clear and Reasonable Warnings

This document was developed by the Office of Environmental Health Hazard Assessment (OEHHA) to assist businesses in locating and understanding relevant provisions in the Article 6 Clear and Reasonable Warnings regulations. For information regarding Proposition 65 safe harbor consumer product exposure warnings provided on the internet and in catalogs, see "Questions and Answers for Businesses: Internet and Catalog Warnings", which is also available on the Proposition 65 Warnings Website.

Q1: Has the Office of Environmental Health Hazard Assessment (OEHHA) issued new regulations concerning the provision of warnings?

A1: Yes, in August 2016 OEHHA adopted amended regulations for the provision of "clear and reasonable" Proposition 65 warnings in Title 27, California Code of Regulations, section 25600, *et seq.*[2] The new regulations will be effective on August 30, 2018, although businesses can begin using warnings that conform with the new regulations at any time.

- Article 6, Subarticle 1 consists of mandatory provisions including definitions of terms that are applicable to all warnings provided under Proposition 65.
- Article 6, Subarticle 2 provides non-mandatory, "safe harbor" methods and content for giving "clear and reasonable" warnings under Proposition 65.

Q2: I have determined that I need to provide a warning. How do I do so?

A2: Guidance for providing a clear and reasonable warning is available in OEHHA's warning regulations. Warnings can be given by a variety of methods depending on the type of exposure (consumer product, environmental, or occupational). You may find it helpful to refer to the side-by-side comparison of the September 2008 and August 2018 ("new") regulations to consider your options, as either can be used until August 30, 2018.

Q3: What kind of testing does a business have to do in order to meet the safe harbor warning requirements?

A3: The warnings regulations do not address the question of *whether* a warning is required; rather, the regulations provide guidance on *how* to provide a warning once a business has made a determination that a warning is required. The warning regulations do not require a business to perform any testing.

[2] All further references are to sections of Title 27, California Code of Regulations unless indicated otherwise.

To guide businesses in determining whether a warning is necessary, OEHHA has developed over 300 regulatory safe harbor levels for Proposition 65 chemicals. A safe harbor level identifies a level of exposure to a listed chemical that does not require a Proposition 65 warning. A business is not required to provide a warning if exposure to a chemical occurs at or below these levels. These safe harbor levels consist of No Significant Risk Levels for chemicals listed as causing cancer and Maximum Allowable Dose Levels for chemicals listed as causing birth defects or other reproductive harm.

Subarticle 1. General

Q4: When do the new regulations take effect?

A4: To allow for a reasonable transition period for businesses to begin providing warnings under the new regulatory provisions, businesses can use either the September 2008 or new regulations until August 30, 2018, at which time the new regulations will become operative and the September 2008 regulations will no longer be available as a safe harbor compliance option.

Q5: If I have to provide a warning, am I required to use the safe harbor warning methods and content described in Article 6?

A5: No, the safe harbor warning methods and content in Article 6 are deemed by OEHHA to be clear and reasonable, and provide a "safe harbor" against enforcement actions for businesses that choose to use them. A business can choose to use other warning methods and content; however, the business might have to defend the warning in legal proceedings if it were challenged by a public or private enforcer as not being clear and reasonable [Section 25600(f)].

Q6: When do I need to provide the new warnings?

A6: The new warnings become operative on August 30, 2018, at which time the September 2008 safe harbor warning methods and content will no longer be operative. The exceptions involve consumer products manufactured prior to August 30, 2018 and labeled in compliance with the September 2008 warning regulations, and products covered by court-approved settlements [Section 25600(b)].

Q7: Does a product available for retail purchase before August 30, 2018 require a new warning?

A7: A consumer product that is *manufactured* prior to August 30, 2018 and labeled with a warning that is compliant with the September 2008 version of the regulations is deemed to be compliant with the new regulations [Section 25600(b)]. In other words, such a product does not require a new warning. The date the product is available for purchase does not determine whether the product should have a new warning.

Q8: Does a product covered by a court-approved warning require a new warning?

A8: A consumer product covered by a court-approved settlement can continue to use any warning methods and content contained in that settlement [Section 25600(e)].

Q9: Can a product that is similar to one covered by a court-approved warning use the court-approved warning instead of the new warning in the regulation?

A9: The new regulations do not prohibit a business that is not a party to a settlement from using warning methods and content incorporated into the settlement. However, if the warning methods or content differ from those in the regulations, the business would not be able to claim safe harbor protection. The business could still defend an enforcement action by arguing such a warning is "clear and reasonable."

Q10: Can a business replace the September 2008 warnings and provide the new warnings immediately?

A10: Yes, during the two-year phase-in period from August 30, 2016 to August 30, 2018, a business can follow the safe harbor methods and content from either the September 2008 regulations or the new regulations [Section 25600(b)].

Responsibility to Provide Warnings

Q11: Who should provide a warning?

A11: Consistent with the Act, OEHHA's new regulations place primary responsibility for providing warnings on product manufacturers, producers, packagers, importers, suppliers or distributors. For consumer product exposures, businesses in the above categories must either provide a warning on the product label or labeling, or provide notice and warning materials to "the authorized agent" for a retail seller and receive an acknowledgment that the notice and materials were received [Section 25600.2(b)]. The retail seller is responsible for placement and maintenance of the warning materials he/she receives from the product manufacturer, producer, packager, importer, supplier or distributor [Section 25600.2(d)]. Businesses should carefully review the new requirements

Q12: Can retail sellers rely on new Section 25600.2(e) now?

A12: No, Section 25600.2(e) of the new regulations does not become operative until August 30, 2018. The phase-in period for the new regulations allows a business to provide *warnings* using the new safe harbor methods and content prior to the operative date of August 30, 2018. However, Section 25600.2(e) is not operative until August 30, 2018.

Q13: If a company is a manufacturer or producer of a consumer product, but does not sell it directly to retailers, how can it comply with the requirement to provide warnings to retail sellers?

A13: A consumer product manufacturer that does not sell directly to retailers has two options for compliance: (1) Provide a warning on the product label or labeling[3]; or (2) Provide both a written notice that a warning is required and warning materials (such as shelf signs) to the packager, importer, supplier or distributor via their authorized agent [Section 25600.2(b)]. Manufacturers and others in the chain of commerce should take appropriate actions to ensure that the warning is passed along to the retailer and ultimately to the consumer [Final Statement of Reasons (FSOR), p. 39]. How that is done will vary from situation to situation. A manufacturer or producer may choose to enter into a contract with other businesses along the chain of commerce for their product and/or the retailer to ensure that the warning is appropriately transmitted to the retailer and end consumer [Section 25600.2(i)].

Q14: If a company manufactures component parts or ingredients that are sold in bulk to other manufacturers or formulators, how can it comply with the requirement to provide a warning, especially if the need for a warning depends on the concentration or the manner of use of the listed chemical in the final product?

A14: A company that manufactures component parts or ingredients that include listed chemicals can comply with the obligation to warn persons who can be occupationally exposed to the bulk product by providing warnings consistent with Section 25606. The company would only have responsibility for a consumer warning if it has knowledge that the end use of the component part or ingredient can expose a consumer to a listed chemical (See FSOR, p. 138). For example, if a manufacturer of a food ingredient knows that the ingredient is typically used in certain types of prepared foods and could thereby result in an exposure under the Act, then the ingredient manufacturer should provide the warning to the product manufacturer [Section 25600.2]. The product manufacturer is then responsible for determining whether the product they are manufacturing causes an exposure to the chemical at a level that requires a warning. If so, the product manufacturer is responsible for passing the information along to its customers or the product retailer [Section 25600.2]. In such a situation, the ingredient manufacturer may also choose to work with the product manufacturer to evaluate whether the product should have a warning and may enter into a contract with product manufacturers to ensure that the warning is transmitted to the retailer and ultimately the consumer [Section 25600.2(i)].

[3] Section 25600.2 sets the responsibilities to provide a warning under the Act, but does not in and of itself provide a safe harbor. A business wishing to claim safe harbor protection must follow the method and content requirements set forth in Article 6, Subarticle 2.

Subarticle 2. Safe Harbor Methods and Content

Q15: What are the type size requirements for safe harbor warnings?

A15: Type size requirements depend on the category of exposure covered by the safe harbor warning. Consumer product exposure warnings must generally be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read and understood by an ordinary individual under customary conditions of purchase or use [Section 25601(c)]. Some safe harbor warnings, such as short-form warnings for consumer products [Section 25602], environmental exposure warnings [Sections 25604, 25605], and several "tailored warnings" [Section 25607.1, et seq.], have specific minimum type-size requirements. You should refer to the safe harbor methods corresponding to the exposure category for which you are providing a warning to determine if there are any applicable type size requirements.

Consumer Product Exposure Warning Methods

For additional information regarding safe harbor consumer product exposure warnings provided on the internet and in catalogs, see "Questions and Answers for Businesses: Internet and Catalog Warnings", which is available on the Proposition 65 Warnings Website.

Q16: What are the ways to provide safe harbor warnings for consumer product exposures?

A16: The safe harbor methods and content for providing a consumer product exposure warning can be found in Sections 25602 and 25603. Section 25602(a) describes four safe harbor warning methods:

- A product-specific warning provided on a posted sign, shelf tag, or shelf sign, at each point of display of the consumer product.
- A product-specific warning provided via any electronic device that automatically provides the warning to the purchaser before purchase without requiring the purchaser to seek out the warning.
- A warning on the label that complies with the content requirements in Section 25603(a); namely, the warning symbol, the signal word, "**WARNING:**", and the applicable warning message.
- A short-form warning on the label that complies with the content requirements in Section 25603(b); namely, the warning symbol, the signal word, "**WARNING:**",

and the applicable truncated warning message. The warning must be in a type size no smaller than the largest type size used for other consumer information on the product and in no case in a type size smaller than 6-point type.

Q17: If a consumer product has exterior packaging, is a warning label required on both the packaging and on the product itself?

A17: No, a "label" is defined as a display of written, printed or graphic material that is printed on or affixed to a product or its immediate container or wrapper [Section 25600.1(i)]. The warning label should be placed in a manner to ensure that consumers receive the warning prior to exposure. A warning must be visible on exterior packaging that is opaque if an exposure requiring a warning can occur upon opening the package [FSOR, p. 258]. A business may also choose to provide a warning on both the exterior packaging and the product itself.

Q18: Can an owner's manual be used for providing a safe harbor warning?

A18: No, a standalone warning in an owner's manual is not a safe harbor warning method for consumer product exposures [FSOR, p. 74]. For some products (specifically diesel engines, passenger vehicles and recreational vessels), owner's manuals are included as part of a safe harbor warning method used in conjunction with another warning method [Sections 25607.14, 25607.16, and 25607.18].

Q19: Can a sign combine two different safe harbor warnings?

A19: It is possible to provide two or more warnings on a single sign. However, the entire applicable warning content for the type of exposure is required for safe harbor warnings in Subarticle 2. Combining the content of multiple warnings into one warning message would generally not comply with the safe harbor requirements. For example, if a vehicle repair facility allowed smoking at its facility such that warnings were required both for the environmental exposure to petroleum products and tobacco smoke, the required warning elements for each situation must be included for the safe harbor. A combined sign would need to be 8 ½ by 11 inches in dimension (designated smoking area requirement), posted at each public entry of the repair facility as well as within the area in which smoking occurred, printed in no smaller than 32-point type (repair facility requirement) with the messages enclosed in boxes to satisfy the safe harbor requirements. [Sections 25607.26, 25607.27, 25607.28, and 25607.29] A simpler method would be to provide separate warnings using the applicable methods and content.

Q20: Can a business provide a general Proposition 65 warning at each public entrance to a store instead of providing warnings for specific consumer products?

A20: No, the safe harbor consumer product exposure warning methods are described in Section 25602, subsections (a)(1)-(4). The safe harbor warning methods in Subarticle 2 do not include a standalone warning at public entrances purporting to cover all possible consumer product exposures. Such a warning would not meet the requirements for safe harbor warnings under the new regulations. Safe harbor warnings must be clearly associated with the product that is the subject of the warning and comply with the other requirements in Subarticle 2.

Consumer Product Exposure Warning Content

Warning Symbol

Q21: Which American National Standards Institute (ANSI) International Organization for Standardization (ISO) number is required for the yellow warning symbol?

A21: The Article 6 regulations did not adopt the ANSI standards for warning symbols, and there is no requirement that the warning symbol color correspond to a specific ISO number. The regulations only require that the warning symbol be "yellow." OEHHA provides sample compliant warning symbols that a business may download and use.

Q22: If a business does not have the ability to print in color, can the business print the warning symbol in black and white?

A22: Yes, if a business does not use the color yellow for other information printed on the label or sign, the business may print the warning symbol in black and white [Section 25603(a)].

Type Size

Q23: What is the minimum type size for consumer product exposure warnings?

A23: For a consumer product exposure safe harbor warning provided on a label pursuant to Section 25602(a)(3), there is no specific type size requirement. Section 25601(c), however, requires that safe harbor consumer product exposure warnings on a label be prominently displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use.

A "short-form" warning may be provided on a product label in accordance with Section 25602(a)(4). This section requires that the entire warning be in a type size no smaller than the largest type size used for other "consumer information" on the product, and in any case the warning must not be in a type size smaller than 6-point type. "Consumer

information" is defined in Section 25600.1(c), and includes warnings, directions for use, ingredient lists, and nutritional information, but does not include the brand name, product name, company name, location of manufacture, or product advertising.

Chemical Names

Q24: Section 25601(b) requires a safe harbor warning to identify "one or more" of the chemicals for which the warning is being provided. What if a business determines that there are five listed chemicals requiring a Proposition 65 warning? Do *all* five chemicals need to be named in the warning?

A24: If a business chooses to follow the safe harbor methods and content in Section 25601(b), the business must include the name of one or more chemicals for which it is providing a warning. Additionally, where a business is providing a warning for both cancer and reproductive toxicity, the warning must include the name of one or more chemicals for each endpoint.

If, for example, there are five possible chemical exposures from a given product, and all five chemicals are listed only as carcinogens, then the business would only be required to name one of those five chemicals in the warning. However, the business may identify any or all of the remaining four chemicals if it chooses to do so. If there are exposures to both carcinogens and reproductive toxicants, a business would be required to name one of the chemicals that is a carcinogen and one of the chemicals that is a reproductive toxicant, but the business could choose to identify more chemicals in the warning. If the warning covers exposure to a chemical that is listed as both a carcinogen and a reproductive toxicant, the warning would only need to name that one chemical, however both endpoints would need to be included in the warning. The business could choose to identify more chemicals covered by the warning [FSOR, p. 199].

Q25: Is it acceptable to use chemical acronyms in a warning? As an example, if a product requires a warning for "diethylhexyl phthalate," is it acceptable to identify "DEHP" instead of the full chemical name in the warning?

A25: The chemical name as it appears on the Proposition 65 list needs to be included in the warning [FSOR, p. 71]. If the abbreviation is included as part of the full chemical name in a warning, the abbreviation alone can be used for subsequent references to the chemical name.

Short-Form Warnings

Q26: When can a business use a short-form warning?

A26: Section 25603, subsections (a) and (b) provide options for safe harbor warning content for consumer products. Subsection (a) is the standard warning content, while subsection (b) allows a business to use the truncated short-form warning content on a

product label. A business may use either the standard or short-form warning content on a "label" for a consumer product exposure [Sections 25602, subsections (a)(3)&(4)]. The short-form warning is not a warning method applicable to a "sign" [Section 25602(a)(1)].

Q27: Can a business provide a short-form warning instead of a specific product, chemical or area exposure warning ("tailored warning")?

A27: No, if there is a tailored warning for that exposure in Subarticle 2, a business cannot use the short-form warning and still claim the safe harbor unless the tailored warning expressly allows the use of the short-form warning [Section 25607(a)].

Q28: Can a short-form warning be placed on the packaging or does it have to be on the product itself?

A28: The short-form warning can be affixed to or printed on a product "label", which includes its immediate container or wrapper [Section 25600.1(i)] .

Q29: Can a short-form warning label be used on any size product?

A29: OEHHA's intent in adding the short-form warning to the safe harbor methods and content was to provide an alternative that could be used on small products or where space was limited. There is no express prohibition, however, on using the short-form warning on larger products. The warning content on the short-form warning must be in a type size no smaller than the largest type size used for other consumer information on the product and in no case smaller than 6-point type.

Q30: Is information required by other agencies such as warning messages, and nutritional information (calories, serving size, etc.) considered "consumer information"? Does that include the headings for those items?

A30: Yes, information such as warnings and nutritional information are "consumer information" for purposes of the minimum type size required for a short-form warning [Section 25600.1(c)]. There is no exception in the definition for headings.

Q31: If the space on a product label is too small and the short-form warning cannot be placed in one line, can the short-form warning be placed in two/three lines?

A31: Yes, there is no requirement that the short-form warning content fit on one line, however, the requirements such as the location of the warning symbol to the left of the warning message, height of the signal word, and the minimum type size must be followed if the business wishes to claim safe harbor protection.

Q32: If a business provides a short-form warning on the consumer product, can the same warning be provided on a website?

A32: Yes, a consumer product warning provided on a website pursuant to Section 25602(b) can use the same short-form warning content that the business is providing on the product. The business may also use a picture of the label on the product for the website warning.

Warnings in Languages Other Than English

Q33: When are warnings required to be provided in languages other than English?

A33: Safe harbor consumer product warnings [Section 25602], environmental warnings [Section 25604], and "tailored" warnings [Section 25607.1, et seq.] require warning content to be provided in other languages under certain circumstances. As an example, if a consumer product sign or label used to provide a warning includes consumer information about a product in a language other than English, the warning must be provided in that language in addition to English [Section 25602(d)]. Similarly, if signage at a business or facility is in a language other than English, then an environmental warning provided on signage by that business or facility must be in that other language in addition to English [Section 25604(a)].

Q34: How can I access warning content in different languages – Spanish, Chinese, French, etc.?

A34: OEHHA has provided warnings translations for businesses on the Proposition 65 Warnings Website, including translations in Spanish, Cambodian, Chinese (traditional and simplified), French, Hmong, Korean, Tagalog and Vietnamese.

Q35: Is a product name considered "consumer information"?

A35: No, a product name is not considered "consumer information" for purposes of determining whether a language needs to be provided in a language other than English. "Consumer information" includes warnings, directions for use, ingredient lists, and nutritional information; it does not include the brand name, product name, company name, location of manufacture, or product advertising [Section 25600.1(c)].

Environmental Exposure Warning Methods

Q36: If a business has determined that occupational exposure warnings are required for an exposure to a listed chemical, and is providing Proposition 65 occupational warnings that are compliant with the Article 6 safe harbor methods and content, does a business also need to provide warnings to visitors for exposures to listed chemicals at the facility?

A36: In general, a business should consider the exposures to listed chemicals that it knows about, and determine if each exposure requires a warning [FSOR, p. 165] If a business has determined that an employee may be exposed to a listed chemical at his

or her place of business at a level that requires a warning, and that a visitor to the facility can be also exposed to a listed chemical at a level that requires a warning, then Proposition 65 warnings should be provided for these exposures. The business should carefully consider the appropriate placement of warnings in the context of the regulations. The methods and content for providing safe harbor environmental and occupational exposure warnings are located in Sections 25604, 25605, and 25606.

Q37: The "environmental exposure" definition states all exposures that are not consumer product or occupational exposures are environmental exposures. It is not clear what type of warning is required when there are combinations of exposures. Are multiple types of warnings required when multiple types of exposures are occurring?

A37: Proposition 65 requires warnings for exposures to listed chemicals. When the regulations were first adopted, exposures were divided into three general categories: consumer product exposures, occupational exposures and environmental exposures. These categories have worked well over the years. It is true that in some circumstances warnings will need to be provided that do not fit neatly into a single category. In that case, more than one warning may be provided for exposures to listed chemicals in a given location. As an example, the regulations for amusement park warnings require a warning to be posted at each public entrance, but also require warnings to be provided separately for consumer products, alcoholic beverages, food, and enclosed parking facilities where such exposures occur on the premises in order for the amusement park to receive safe harbor protection [Section 25607.22(d)].

Q38: The regulations for environmental exposures require the warning to include a "map" [Section 25604(a)(2)(B)]**. Does that mean a floor plan of the property or a map of the area showing the location?**

A38: A "map" created pursuant to these regulations should clearly delineate the affected area as distinct from the surrounding unaffected areas. A map of an area where exposures requiring a warning can occur (such as a community adjacent to an industrial facility that is causing the exposures) should include landmarks such as street names, rivers, or other identifying features to allow people to readily recognize the area indicated. In some situations, such as a facility where exposures requiring a warning can occur on the facility's premises, a written description of the source of exposure, a floor plan delineating the affected area(s), or other graphic may be more clear (See FSOR, p.122).

Environmental Exposure Warning Content

Q39: How specific must the description of the source of exposure be in an environmental warning? Must a specific area be described for each source of

exposure or for each chemical present, or only for the chemical listed in the warning?

A39: The specific area must be described in the warning only for the chemical or chemicals that are named in the warning. Examples of how a warning can identify the source of the exposure and be provided in a manner that clearly associates it with the exposure can be found in the tailored warning section of the regulation (see Sections 25607.20 and 25607.21 (enclosed parking facilities), Sections 25607.24 and 25607.25 (petroleum products), Sections 25607.26 and 25607.27 (service stations and repair facilities), and Sections 25607.28 and 25607.29 (designated smoking areas)).

Where a warning is being provided for multiple chemicals and/or multiple exposures, the warning should describe the area in which an exposure to those chemicals can occur [FSOR, p. 130]. It may be appropriate in some circumstances to provide warnings in more than one location in a facility so that the warning will be clearly associated with the source(s) of exposure. For example, posting a sign at the entry of a facility that purports to provide a warning for an exposure that is only likely to occur in one area of the facility, such as in an art studio on the third floor of a building, would not be sufficiently associated with the source of the exposure. Such a warning should be posted at entrances to that area of the third floor. On the other hand, if a particular chemical exposure can occur throughout a facility, for example exposures to a solvent from paint used throughout a large freestanding art studio, a warning at the studio entrance naming the chemical and the source (paint) may be appropriate.

Environmental exposure warnings must be provided in a conspicuous manner and under conditions that make the warning likely to be seen, read, and understood by an individual in the course of normal daily activity [Section 25601(d)]. The warning should be provided close enough to the source of exposure for the person seeing the warning to determine where and how they may be exposed [FSOR, p. 120].

Warnings are not required for the mere "presence" of listed chemicals. The business should determine if there is likely to be an exposure to a listed chemical at a level that requires a warning.

Occupational Exposure Warnings

Q40: Are professional or industrial use-only products covered by this regulation?

A40: If a business has determined that the only exposures to a listed chemical that require a warning will be occupational, then the business can follow the safe harbor occupational exposure methods and content described in Section 25606. The term "occupational exposure" is defined in Section 25600.1(k) as "an exposure to any employee at his or her place of employment".

Q41: Section 25606(a) states that a warning is not required on products that meet the requirements of the Hazard Communication Standard (HCS). If a product contains a Proposition 65 chemical, but the quantity is not enough to trigger classification as a carcinogen or reproductive toxicant under the HCS, does it still require a Proposition 65 warning?

A41: Proposition 65 imposes separate warning requirements from the HCS. Section 25606 provides that a business can comply with Proposition 65 by complying with state and federal occupational training and warning requirements *when a warning is required* under the federal or California HCS, or the California Pesticides and Worker Safety requirements. In the event that there is an occupational exposure to a Proposition 65 listed chemical with no warning requirement for the chemical under these laws, *a Proposition 65 warning may still be required* [FSOR, p. 29]. Section 25606(b) provides businesses the option to use safe harbor warning methods and content for an exposure to a Proposition 65 listed chemical in an occupational setting.

Q42: Can a business place the Proposition 65 warning on a Safety Data Sheet (SDS)?

A42: Safety Data Sheets (SDS) are outside the scope of this regulation, as OEHHA cannot prescribe the content of forms under the authority of a federal or other state agency. While the SDS may in some circumstances be used to provide occupational exposure warnings, they are not a safe harbor warning method for other exposure types such as consumer product or environmental exposures covered by Article 6.

Specific Exposure Warnings

Q43: There is a specific exposure warning ("tailored warning") for my product in the new regulations. Does that mean a warning is now required?

A43: The fact that there is a tailored warning for a particular product (or place) does not mean that a warning is required. A warning is required only when there is an exposure to a listed chemical from the product. As stated in Section 25600(a), the Article 6 regulations do not determine whether a warning is required, and a business should make the determination of whether a warning is required for a specific exposure. The business may use the safe harbor warning methods in Subarticle 2 to provide a clear and reasonable warning. Where a specific product, chemical or area exposure warning has been adopted in regulation, the specific warning must be used rather than the general warning (i.e., consumer product exposure or environmental) in order to take advantage of the safe harbor. [Section 25607]

Q44: Can I use a point-of-sale warning for exposures to Bisphenol A (BPA) in canned and bottled foods and beverages as a safe harbor warning?"

A44: No, the point-of-sale warning option for exposures to BPA in canned and bottled foods and beverages was a temporary regulation that expired on December 30, 2017 and is no longer a safe harbor option for businesses. Businesses should refer to the more general provisions of Article 6, Subarticle 2 for the current regulations concerning safe harbor warning methods and content for consumer product exposures.

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Environmental, Safety & Health
US TSCA Experience

Our Environmental, Safety & Health Practice has deep experience representing clients on the full range of matters relating to the Toxic Substances Control Act (TSCA) and related statutes. It includes providing counsel and advice to chemical and product manufacturers, processors, users, marketers and distributors through the complete product life cycle, beginning with research and development, continuing through registration, manufacturing, sale, distribution (including import and export matters), recycling and disposal.

We also analyze, comment on and, where needed, challenge rules, and defend against agency enforcement actions and third-party claims. We have been heavily involved in the ongoing efforts to modernize TSCA, including advising clients on issues relating to TSCA legislative changes, working with members of the US Congress on TSCA issues and testifying before Congress on TSCA reform.

Why Choose Us

Our environmental, safety and health lawyers are among the industry's most experienced professionals in matters related to TSCA. In addition to their experience on behalf of a wide range of clients, several of our lawyers earned degrees in the sciences or have worked with industry or in government, including a former Assistant Administrator of the US Environmental Protection Agency (EPA) in charge of that agency's implementation of TSCA.

Representative TSCA Experience

- Advising chemical companies in connection with the preparation and submission of TSCA Premanufacture Notifications (PMNs) and Significant New Use Notices (SNUNs).
- Advising chemical manufacturers and importers on exceptions to the TSCA PMN requirement, including the low volume exemption (LVE), research and development (R&D) exemption, test marketing exemption (TME), low release and low exposure (LoREX) exemption and polymer exemption.
- Advising a global manufacturer of materials used in the semiconductor and coatings industries on issues relating to Significant New Use Rules (SNURs), reporting requirements and compliance with Low Volume Exemption (LVE) limits and recordkeeping.
- Advising a global consumer products manufacturer on TSCA Test Marketing Exemption (TME) requirements, SNUR recordkeeping and notification issues, and PMN submissions to EPA.
- Advising numerous chemical companies and processors on issues relating to submission of notifications under EPA's TSCA Inventory Reset Rule.
- Advising companies on issues relating to EPA's risk evaluations for the "first ten" chemical substances, including EPA's scoping and problem formulation documents.
- Advising a global manufacturer of chlor-alkali and epoxy products on a wide range of TSCA matters, including issues relating to SNURs, imports and exports, TSCA Inventory Reset reporting, risk evaluations, PMNs, Chemical Data Reporting (CDR), Nanomaterial Reporting Rule requirements, TSCA section 8(e) "significant risk information" submissions and substantiation of confidential business information (CBI) claims.
- Advising chemical manufacturers, processors, mining entities and other companies on compliance with EPA's TSCA mercury reporting rule.
- Representing a major metal-based chemistry manufacturer in connection with PMNs and SNUNs, as well as reporting and disclosure requirements.
- Advising US chemical manufacturers in connection with the first US EPA TSCA Chemicals Work Plan assessments of chlorinated solvents, which have been targeted for possible use restrictions under TSCA Section 6.

- Conducted an internal TSCA compliance investigation for a specialty chemicals company that led to voluntary disclosure to US EPA of identified concerns regarding a key product and secured a negotiated consent agreement with minimal penalty and full ability to continue use.
- Negotiation of PMNs in the context of enforcement actions against an importer of chlorinated paraffins; also the subject of a TSCA Chemicals Work Plan and potential ban.
- Organized and represented a consortia of producers of hazardous air pollutants in negotiating enforceable consent agreements (ECAs) in lieu of TSCA Section 4 test rules, including first ECA to use pharmacokinetic modeling in lieu of testing.
- Advising an international mining company on complying with PMN requirements, submitting bona fide information requests for confidential listings on the TSCA Inventory, and reporting information under US EPA's Chemical Data Reporting (CDR) rule.
- Advising an international electronics manufacturer on PMN requirements and exemptions, as well as TSCA Section 13 import certification requirements.
- Advising a global manufacturing company on US EPA's regulation of articles under TSCA.
- Initiated TSCA audits of divisions of a US chemical company, prepared related audit policy disclosures for key findings and led engagement with US EPA that secured a negotiated resolution with limited business impact on the company.
- Advised a major chemical company on correction of TSCA reporting concerns, management of Section 8(e) "substantial risk" information disclosure obligations, Significant New Use Rule (SNUR) notification requirements, development of PMNs and other related issues to ensure compliance, satisfy customer requests and limit enforcement risk.
- Advising companies on the requirements of TSCA Section 8(e) and US EPA's interpretation of Section 8(e) and enforcement actions.
- Assisting companies with submissions to US EPA under TSCA Section 8(e).
- Advising companies on TSCA Section 8(c) recordkeeping requirements for "significant adverse reactions" information.
- Advising chemical companies on TSCA issues arising in connection with toll manufacturing agreements.
- Assisting formulators of methylene chloride-based paint strippers in responding to their designation as "priority products" under the California Green Chemistry Initiative.
- Advising chemical manufacturers on compliance with TSCA Section 4 testing rules and Section 8 reporting rules.
- Represented a national trade organization and its members in inquiry before US EPA to clarify TSCA regulatory status of a common product potentially impacted by inconsistent treatment and new information generated under the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Advising an international chemical company on TSCA inventory modification procedures and reporting requirements.
- Assisting chemical companies and product manufacturers on SNUR requirements.
- Advising chemical manufacturers and processors on import and export requirements under TSCA Sections 12 and 13.
- Advising companies on the requirements of US EPA's CDR rule.
- Negotiating TSCA Section 5 consent orders on behalf of chemical manufacturers and importers.
- Advising clients on the TSCA requirements relating to submission and protection of confidential business information (CBI).
- Counseling a global chemical company on TSCA issues affecting nanotechnology, including US EPA's TSCA Section 8 reporting rule for nanomaterial substances.
- Advising a US biotechnology company on the regulation of microorganisms under TSCA and compliance with the Microbial Commercial Activity Notice (MCAN) requirement and other applicable TSCA regulations.

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Environmental, Safety & Health
US EPA Issues TSCA Inventory Reset Rule

Overview

On June 22, 2017, as required by the amended Toxic Substances Control Act (TSCA), the US Environmental Protection Agency (US EPA) issued its rule to "reset" the TSCA Inventory. The rule requires every chemical manufacturer and importer to notify US EPA of each chemical substance it manufactured or imported for a non-exempt commercial purpose in the US during the 10-year period ending June 21, 2016 (the "lookback period"). Manufacturers and importers must provide this notification to US EPA within 180 days from the date on which the rule is formally published in the Federal Register. Each chemical substance for which US EPA receives such a notification will be designated as "active" on the TSCA Inventory.

The Inventory Reset Rule was formally published in the Federal Register on August 11, 2017. The deadline for manufacturers and importers to submit the required notifications to US EPA is February 7, 2018.

The rule also gives chemical processors the option to report to US EPA any chemical substance they processed during the same lookback period, but they must do so within 420 days from the rule's Federal Register publication date. The deadline for processors to submit their notifications to US EPA is October 5, 2018. Processors are given an extended submission period to allow them to review a "draft" version of the revised Inventory that US EPA will issue approximately 60 days after the close of the 180-day reporting period for manufacturers and importers. Processors thus will have roughly 180 days after US EPA issues the draft revised Inventory to identify any chemical substances that manufacturers have failed to designate as "active" and submit notices to US EPA for the substances they processed during the lookback period, in order to keep such substances from being designated as inactive.

Any chemical substance not reported to US EPA by a manufacturer, importer or processor by the applicable deadline will be designated as "inactive" on the Inventory. Once the Inventory "reset" is finalized, no one may manufacture, import or process an inactive substance without giving US EPA prior notice not more than 90 days before the anticipated date of manufacturing, importing or processing.

Inventory Transition Period

While a company may not manufacture, import or process an inactive substance without giving prior notice to US EPA, the rule provides that a substance actually will not be designated as inactive on the TSCA Inventory until 90 days after US EPA has "identified" the substance for inactive designation. US EPA calls this 90-day time frame the Inventory "transition" period. To kick off the transition period, US EPA will publish the first version of the revised Inventory on its website "as soon as practicable after compilation." This version of the Inventory will be accompanied by a "signed action" that will "identify" chemical substances for inactive designation.

Because the inactive designation will not be "effective" at that point, companies may continue to manufacture, import or process a substance after it has been identified for inactive designation, but they must notify US EPA of their activity prior to the end of the transition period, when the substance is actually designated as inactive, in order to continue their activity. Otherwise, they will have to cease their activity at the end of the 90-day transition period, and not resume it until they have given notice to US EPA (after which US EPA will designate the substance as active).

Reporting Process and Content

Under the rule, all reports must be filed electronically through US EPA's CDX system, using forms that US EPA has developed.

For "retrospective" reporting (i.e., notifying US EPA of substances manufactured, imported or processed during the lookback period), companies must use Notice of Activity (NOA) Form A to submit the information. Companies will be able to select chemicals for reporting from a "pick list" in the CDX system. Non-confidential substances will be listed by the Chemical Abstracts (CA) Index name and Chemical Abstracts Service registry number (CASRN). Substances on the confidential portion of the Inventory will be listed by EPA accession numbers and generic names. Any company reporting a confidential substance that wishes to maintain the confidential business information (CBI) claim for the substance's chemical identity must indicate so on the NOA Form A. If the company does not do so, US EPA will designate the substance as active, but will list it on the public portion of the Inventory.

For "prospective" reporting – i.e., giving US EPA notice of intent to manufacture or import a substance and move it from the inactive list to the active list – companies must use NOA Form B. In addition to providing information about the company and the substance, NOA Form B requires a submitter to indicate the anticipated date when manufacturing, processing or importing of the substance will begin. A company intending to manufacture, import or process an inactive substance must submit NOA Form B no more than 90 days before the anticipated date of the activity. Similarly, as noted, any company that continues to manufacture, import or process a substance during the transition period after the substance has been identified for inactive designation (but before its formal designation as inactive) may submit NOA Form B to US EPA before the end of the 90-day transition period. Otherwise, the company must cease its activity until such time as it files NOA Form B.

Confidentiality Claims

Under the rule, any manufacturer, importer or processor may seek to maintain an existing CBI claim for the chemical identify of a substance on the confidential portion of the TSCA Inventory, regardless of whether of whether it had asserted the original CBI claim.

The rule allows companies submitting retrospective reports using NOA Form A to seek to maintain existing CBI claims for chemical identity without having to provide substantiation for the CBI claim. This is because the amended TSCA requires US EPA to review CBI claims for chemical identity for active chemicals within five years after the Inventory is reset. US EPA's review plan will include mandatory requirements for substantiating a CBI request for chemical identity reported in a NOA Form A and will specify when the substantiation must be provided to US EPA. A company may voluntarily provide "early" substantiation for the CBI claim when it submits NOA Form A, however, and would not have to do so later during US EPA's review process as long as the time period between the date of such early substantiation and the date established in US EPA's review plan is not more than five years. If a CBI claim is not asserted by a manufacturer, importer or processor, US EPA will move the substance from the confidential portion of the Inventory to the non-confidential one.

Any company wishing to maintain an existing CBI claim for a substance that was added to the confidential portion of the TSCA Inventory prior to June 22, 2016 must submit a NOA Form A themselves and advise US EPA that the CBI claim should be maintained. Even if a confidential substance is exempt from the retroactive reporting requirement because a Notice of Commencement (NOC) was submitted to US EPA for it during the lookback period, US EPA will not keep the substance on the confidential portion of the TSCA Inventory unless it receives a notice from a manufacturer, importer or processor specifically asserting that the CBI claim should be maintained. Moreover, even if a company is relying on a CDX receipt from another manufacturer, it must submit a notice asserting the CBI claim for the substance if it wishes to maintain the claim. Otherwise, it runs the risk that no one else might assert the CBI claim, and US EPA would designate the substance as active, but list it on the non-confidential portion of the Inventory.

Although substantiation is not required for CBI claims for chemical identity when a NOA Form A is submitted, companies must provide substantiation for a CBI claim that is made in retrospective submissions for any other information relating to the substance.

With regard to CBI claims asserted in prospective reporting using NOA Form B, the rule requires that substantiation for any such claims must be provided to US EPA within 30 days after the NOA Form B is submitted. If the CBI substantiation is not received within 30 days, US EPA will move the substance from the confidential portion of the TSCA Inventory to the public portion.

Withdrawing and Correcting Notices

The rule allows a manufacturer, importer or processor to withdraw its submitted NOA Form A at any time prior to the applicable deadline for submission (i.e., 180 days after the Federal Register publication date for manufacturers and importers and 420 days for processors). Relatedly, a manufacturer, importer or processor may correct an error in its NOA Form A by withdrawing the submission and submitting a new, corrected NOA Form A prior to the applicable deadline.

A company may not withdraw a NOA Form B, however, without US EPA's approval. Once US EPA receives the NOA Form B advising the agency of the company's intent to manufacture import or process an inactive substance, the agency will redesignate the substance as active. If US EPA has not yet redesignated the substance as active, the agency may allow the NOA Form B to be withdrawn and keep the substance designated as inactive. If US EPA already has designated the substance as active, however, it will not redesignate the substance back to inactive status.

Similarly, if US EPA has moved a substance from the confidential portion of the Inventory to the public portion based on a submitted NOA Form B, it will not revert the substance back to a CBI substance.

Exemptions from the Notice Requirement

Under the rule, certain substances do not have to be reported to US EPA for purposes of the Inventory reset, including:

- Substances that are generally excluded from Inventory reporting based on the low volume exemption, LoREX exemption, polymer exemption, test marketing exemption or R&D exemption.
- Naturally occurring substances.
- Substances that were already reported in response to the 2012 or 2016 Chemical Data Reporting (CDR). These substances will be automatically designated as active and will make up an "interim" list of active substances that US EPA will issue. (Note: A company must file a NOA Form A for any substance on the confidential portion of the Inventory if the company wishes to maintain the CBI claim.)
- Substances that were added to the Inventory during the lookback period pursuant to a Notice of Commencement (NOC) submitted to US EPA during that period.
- Substances added to the TSCA Inventory since June 22, 2016.

In addition to these exemptions, the rule provides that a manufacturer (including importers) is not required to submit a notice for a substance covered by the lookback period if the manufacturer has "evidence in the form of a CDX receipt" from another manufacturer showing that the other manufacturer submitted a notice to US EPA for the substance.

US EPA established this exemption in response to concerns expressed by stakeholders about duplicative reporting of substances. In the preamble to the rule, however, US EPA cautions that any manufacturer relying on the exemption "bears the risk" if the other manufacturer later withdraws its notice and the substance is subsequently designated as inactive. As noted, once a substance has been formally designated as inactive, a company cannot manufacture, import or process the substance until the company submits NOA Form B to US EPA.

Additionally, as noted, a company seeking to maintain an existing CBI claim for the chemical identity of a substance must submit a NOA Form A and assert the CBI claim themselves even if a company is relying on a CDX receipt from another manufacturer. Otherwise, they run the risk that other company did not assert the CBI claim or even that the other company might withdraw its submission entirely.

Next Steps

For more information about the TSCA Inventory Reset Rule or any other aspect of TSCA, please contact one of the individuals listed in this publication.

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Environmental, Safety & Health
US EPA Issues TSCA Prioritization Rule

Overview

On June 22, 2017, the US Environmental Protection Agency (US EPA) issued its rule for prioritizing chemical substances for purposes of risk evaluation, as required by the amended Toxic Substances Control Act (TSCA). The rule was published in the Federal Register on July 20, 2017.

Under the amended TSCA, US EPA is required to prioritize chemical substances on the TSCA Inventory as "high priority" or "low priority." US EPA then must conduct risk evaluations on the high-priority substances.

The rule sets forth a three-step process that US EPA will follow for prioritizing chemical substances on the TSCA Inventory: (1) initiation; (2) proposed designation; and (3) final designation. Once formally initiated (Step 1), the prioritization process must last at least nine months, but cannot last longer than 12 months.

US EPA had proposed a "pre-prioritization" step to precede the proposed designation, during which time the agency would identify a pool of substances based on certain criteria identified in TSCA and gather information on these substances before formally initiating the prioritization process. In response to stakeholder comments, US EPA deleted the pre-prioritization step from the final rule and will be taking further public comment on how the agency will identify candidate substances for prioritization.

The preamble to the rule states that US EPA's "primary objective" will be to identify high-priority substances that have the "greatest hazard and exposure potential" first. The preamble further states that US EPA will designate the priority of a chemical substance as a whole under its conditions of use and will not limit its designation to a specific use or subset of uses of the substance. The preamble adds, however, that US EPA will not necessarily consider every activity involving a substance to be a condition of use and that the agency has determined that certain activities should not be considered conditions of use. To that end, US EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance it is prioritizing and consider those conditions of use when prioritizing the substance.

Even though the rule does not include a formal pre-prioritization step, US EPA "expects to consider the existence and availability of risk-based information on a candidate substance before initiating the prioritization process" and "resolve any concerns" about the sufficiency of information on a substance "before subjecting that chemical substance to the prioritization process." US EPA "generally expects" to use a "tiered" approach to information gathering, but will exercise its authorities under the amended TSCA to require submission or generation of new data as necessary.

The amended TSCA requires US EPA to give preference to substances listed in the agency's 2014 TSCA Work Plan that are persistent and bioaccumulative, that are known human carcinogens and/or have high acute and chronic toxicity. Additionally, because the amended TSCA requires that 50% of all ongoing risk evaluations be conducted on substances listed on the Work Plan, the agency intends to draw at least 50% of the high-priority substances from the Work Plan.

Although substances newly added to the TSCA Inventory are candidates for prioritization, the preamble to the rule states that such substances are not likely to be high-priority candidates given that they recently have undergone premanufacture notice (PMN) review.

Initiation of the Prioritization Process

During the initiation step, US EPA will formally announce (via a notice in the Federal Register) that a substance is a "candidate" for prioritization and give the public 90 days to submit relevant information about it. US EPA can extend the comment period for up to an additional three months in order to receive or evaluate information from a TSCA test order.

After the close of the 90-day public comment period, US EPA will "screen" the candidate substance against several "criteria and considerations" outlined in the amended TSCA: (1) the substance's hazard and exposure potential; (2) the substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the substance near significant sources of drinking water; (5) the substance's conditions of use or significant changes in conditions of use; (6) the substance's production volume or significant changes in production volume; and (7) other risk-based criteria that US EPA determines to be relevant to the priority designation of the substance.

Proposed Designation as High-Priority or Low-Priority

Based on the results of the screening review, US EPA will propose that a chemical substance be designated as either high-priority or low-priority. The proposed designation also will include an identification of the information, analysis and bases to support the proposed designation. US EPA will take public comment on the proposed designation for 90 days.

As noted, US EPA expects to select as high-priority substances chemicals with the greatest hazard and exposure potential first. The rule states that the agency may propose a high-priority designation based on one or more conditions of use of the substance. The rule further states that US EPA will propose to designate a substance as a high-priority substance if there is insufficient information to enable the substance to be designated as a low-priority substance (after any extension of the comment period during initiation of the prioritization process for information gathering purposes).

Relatedly, US EPA will propose a substance for low-priority designation where the information on hazard and exposure under the conditions of use for the substance "is sufficient to establish that a risk evaluation is not warranted." The preamble to the rule notes that, before a substance can be designated as low-priority, TSCA requires US EPA to determine that the substance does not meet the definition of a high-priority substance under any of the conditions of use.

TSCA prohibits US EPA from considering costs or other non-risks factors in making a proposed priority designation.

Final Designation as High-Priority or Low-Priority

US EPA will finalize the designation of a substance via an announcement in the Federal Register. When the final designation is issued, US EPA also will publish an identification of the information, analysis and basis used to support the designation. US EPA also will identify which conditions of use were the primary bases for the priority designation.

If the substance is designated as high-priority, US EPA must initiate a risk evaluation of the substance. If the substance is designated as low-priority, US EPA will not conduct a risk evaluation of it – unless and until the agency has information that causes it to reconsider the designation.

A low-priority designation is a final agency action under the amended TSCA and is subject to judicial review. A high-priority designation, however, is not a final agency action.

As noted, the amended TSCA prohibits US EPA from considering costs or other non-risk factors in the designation of a chemical substance as high- or low-priority.

Scientific Standards

The rule incorporates certain standards from the amended TSCA statute regarding how US EPA will utilize scientific information when making priority determinations. The rule states that US EPA's proposed priority designations and final priority designations will be consistent with the standards, including those relating to best available science and weight of the scientific evidence.

Repopulation of High-Priority Substances

The amended TSCA requires US EPA to designate at least 20 chemical substances as high-priority within three and a half years after enactment (i.e., by December 2019). At least 20 other substances also must be designated as low-priority within that same time frame. Further, once US EPA completes a risk evaluation on a chemical substance, it must begin a risk evaluation on another high-priority substance to ensure that at least 20 substances are undergoing risk evaluation at any time. Consequently, US EPA must continually designate high-priority substances. In that regard, US EPA generally expects to identify the particular risk evaluation that the new high-priority substance will replace.

Next Steps

For more information on the proposed prioritization rule or any other aspect of TSCA, please contact one of the individuals listed in this publication.

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Environmental, Safety & Health
US EPA Issues TSCA Risk Evaluation Rule

Overview

On June 22, 2017, the US Environmental Protection Agency (US EPA) issued its rule outlining the process by which it will conduct risk evaluations on chemical substances under the amended Toxic Substances Control Act (TSCA), to determine whether the substances present an unreasonable risk of injury to health or the environment under the conditions of use. The rule was published in the Federal Register on July 20, 2017.

The rule identifies the steps in US EPA's risk evaluation process, including the scope of the risk evaluation, hazard assessment, exposure assessment, risk characterization and risk determination. US EPA will use this process for (1) the first 10 chemical substances that it selected for risk evaluation from its Work Plan chemicals list last November (as required by the amended TSCA); (2) substances designated as high-priority substances during the prioritization process; and (3) substances for which US EPA initiates a risk evaluation in response to manufacturer requests.

US EPA is required to complete a risk evaluation within three years, with the possibility of extending the timeline by six months for certain reasons. Rather than examining "all" conditions of use for a substance, US EPA intends to conduct the risk evaluation on the conditions of use "that raise the greatest potential for risk" as identified in the scoping document, which the agency will develop at the outset of the risk evaluation process. The rule states, however, that US EPA may conduct a risk evaluation in phases and make risk determinations on one or more conditions of use while other conditions of use remain under evaluation. If US EPA conducts a risk evaluation in phases, the agency will complete the full risk evaluation on all the conditions of use identified in the scope within the time frame provided in the amended TSCA.

Each risk evaluation must: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure.

The rule incorporates TSCA's statutory science requirements, including best available science and weight of the scientific evidence.

Unreasonable Risk

TSCA does not define "unreasonable risk" and the rule does not either. The preamble to the rule notes, however, that US EPA may weigh a variety of factors in determining whether a substance presents an unreasonable risk, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; and the population exposed (including any susceptible populations), the severity of hazard, the nature of the hazard, the irreversibility of hazard, and uncertainties.

Conditions of Use

US EPA will examine the conditions of use for a substance "that raise the greatest potential for risk," rather than assessing "all" conditions of use. The preamble to the rule states US EPA will use its discretion to identify the conditions of use and that the agency "may, on a case-by-case basis, exclude certain activities … in order to focus its analytical efforts on those exposures that are likely to present the greatest concern."

US EPA will identify any conditions of use excluded in the draft scoping document. The final scoping document will specify the conditions of use that US EPA expects to consider in the risk evaluation and will also identify whether particular conditions of use have been excluded. The preamble to the rule states that, as a general matter, US EPA will not evaluate intentional misuses of a substance, as well as "associated disposal" and "legacy disposal" that is not related to the ongoing or prospective manufacturing, processing or distribution of the substance.

As noted, because of the possible need to address a particular condition of use expeditiously (such as when a single use presents an unreasonable risk to the population as a whole or to a specific subpopulation), the rule states that US EPA may complete risk evaluations in phases and make risk determinations on individual conditions of use or categories of conditions of use at any time once the final scoping document is published.

The preamble to the rule also states that US EPA may consider potential risk from non-risk TSCA uses in evaluating whether a chemical substance presents an unreasonable risk, although the uses would not be within the scope of the risk evaluation. The preamble explains that the potential risks of non-TSCA uses "may help inform US EPA's risk determination for the exposures from uses that are covered under TSCA," for example, "as background exposures that would be accounted for" if US EPA decides to evaluate aggregate exposures for a substance.

Potentially Exposed or Susceptible Subpopulations

The amended TSCA requires US EPA to evaluate the risks that a chemical substance may present to a "potentially exposed or susceptible subpopulation." The statute defines this term as "a group of individuals within the general population identified by [US EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly." The rule incorporates this statutory definition without change.

Aggregate and Sentinel Exposure

The amended TSCA requires US EPA to document whether it has considered aggregate or sentinel exposure in a risk evaluation but does not define those terms. The rule defines "aggregate exposure" as "the combined exposures to an individual across multiple routes and across multiple pathways." (The rule defines "pathways" as "the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil and air.") The rule also defines "sentinel" exposure as "the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures."

Categories of Chemical Substances

The rule states that the agency has the authority to conduct risk evaluations on categories of chemical substances in addition to risk evaluations on individual substances.

Information Collection

The rule states that US EPA "generally expects" to initiate a risk evaluation when the agency believes that "all or most of the information necessary to perform the risk evaluation already exists and is reasonably available." US EPA expects to use its "authorities under TSCA and other information gathering authorities" to obtain the information needed to perform a risk evaluation before initiating the risk evaluation. The preamble to the rule adds that "there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process" and states that US EPA may use its authorities to obtain or require the generation of additional information even after the risk evaluation has been initiation. The preamble further states that US EPA also will require longer-term testing to address data gaps.

For identified data needs, US EPA "may" issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed by using its TSCA information collection, testing and subpoena authorities to require submission or generation of new data "as appropriate."

The Risk Evaluation Process

US EPA is proposing a risk evaluation process that consists of seven aspects: (1) scope; (2) hazard assessment; (3) exposure assessment; (4) risk characterization; (5) peer review; (6) unreasonable risk determination; and (7) additional publicly available information.

1. Scope

The amended TSCA requires US EPA to define the scope of the risk evaluation no later than six months after initiating the risk evaluation. Although not required by the amended TSCA, the rule states that US EPA will provide a draft scope for a 45-day public comment period during this six-month time frame.

The scope will identify the conditions of use, hazards, exposures and any potentially exposed or susceptible subpopulations that the agency expects to consider in the risk evaluation. The scope will also include additional information, such as models, screening methods and any accepted science policies, expected to be used during the risk evaluation, along with a conceptual model that will describe the "actual or predicted relationships between the chemical substance and the receptors, either human or environmental." The scope will further include an "analysis plan" that will identify the approaches and methods the US EPA plans to use to assess exposure, effects and risk.

2. Hazard Assessment

The hazard assessment will identify the types of adverse health or environmental effects that can be caused by exposure to the chemical substance in question. For human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope. US EPA will use an "appropriate combination" of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population and "any other information or methodology consistent with scientific standards." An environmental hazard assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response and "may be conducted using reasonably available information from field or laboratory data, modeling strategies, and species extrapolations, if needed." The rule commits US EPA to using the best available science and a weight of the evidence approach.

3. Exposure Assessment

As required by the amended TSCA, the exposure assessment will take into account the likely duration, intensity, frequency and number of exposures under the conditions of use. For human health exposure, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media and any other relevant, scientifically valid information or methodology. An environmental health exposure assessment, will characterize and evaluate the interaction of the chemical substance with any ecological characteristics identified in the scope. Exposure information will be reviewed in a manner consistent with best available science and weight of the evidence.

4. Risk Characterization

The rule states that the risk characterization "will integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including

any potentially exposed or susceptible subpopulation(s)) identified in the final scope and ecological characteristics for the conditions of use within the scope." It will also describe whether aggregate or sentinel exposures were considered; take into account the likely duration, intensity, frequency and number of exposures under the condition(s) of use; and describe the weight of the scientific evidence for the identified hazards and exposures. As required under the amended TSCA, the risk characterization cannot consider costs or other nonrisk factors.

5. Peer Review

US EPA will conduct peer reviews on each risk evaluation and will take public comment on the charge questions given to peer reviewers. However, US EPA will not seek peer review of the actual risk determination (i.e., US EPA's conclusion regarding whether a given risk is unreasonable). The plan for peer review will be set forth in the scoping document for the risk evaluation.

6. Unreasonable Risk Determination

In the final step of the risk evaluation, US EPA will determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. US EPA will make individual risk determinations for all uses identified in the scope. As US EPA may make early determinations on one or more conditions of use, risk determinations may be published in multiple documents or in a single document containing all risk determinations for all identified uses. If the determinations are published in multiple documents, the final determination will be a composite document of all determinations made. US EPA will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury.

A determination that a condition of use does not present an unreasonable risk is a final agency action and is subject to judicial review. A determination that a condition of use presents an unreasonable risk is not a final action and is not subject to judicial review. This is because when it concludes that a risk is unreasonable, the agency must initiate a rulemaking under TSCA section 6 to address the risk. Because any rule would apply only to the condition(s) of use that present an unreasonable risk, any other identified conditions of use will not be subject to risk management. In the draft and final risk evaluation documents, US EPA will clarify specifically which condition(s) of use warrant risk management and which do not.

7. Additional Publically Available Information

US EPA will make publicly available (1) the draft scope; (2) all notices, determinations, findings, consent agreements and orders; (3) any information required to be provided by section 4 of TSCA; (4) a nontechnical summary of the risk evaluation; (5) a list of the studies considered in carrying out the risk evaluation; (6) each determination as to whether the chemical substance presents an unreasonable risk under one or more conditions of use, along with an identification of the information, analysis and basis used to make the determination; (7) the final peer review report, including the agency's response to peer review comments; and (8) the response to comments received on the draft scope and draft risk evaluation.

Manufacturer Requested Risk Evaluations

The amended TSCA allows a manufacturer or group of manufacturers to submit requests for US EPA to conduct risk evaluations on chemical substances that they manufacture (including import). Manufacturers may request that US EPA conduct a risk evaluation on only the conditions of use "that are of interest to the manufacturer." However, even if a manufacturer (or group of manufacturers) requests that the risk evaluation be based on a just a subset of the conditions of use, the rule states that US EPA may include additional conditions of use in the risk evaluation. US EPA will determine the additional conditions of use during the process of deciding whether to grant or deny the manufacturer request.

As part of the request, a manufacturer (or group of manufacturers) must submit "all of the information necessary to complete risk evaluation for the requested conditions of use." The information includes, at a minimum, all known names of the chemical substance, chemical identity, CAS number and molecular structure.

US EPA will give preference to manufacturer requests that demonstrate that restrictions imposed by one or more states have the potential to have a significant impact on interstate commerce, health or the environment, followed by a preference based on the order in which a request is received. These preferences, however, are versus other manufacturer requests. The amended TSCA prohibits US EPA from giving manufacturer-requested risk evaluations priority over other risk evaluations.

US EPA plans to take public comment on a manufacturer request for "at least 45 days." The agency anticipates that roughly 195 days will be needed from the time that it receives a manufacturer request to the time that it actually initiates the risk evaluation, if US EPA grants the request. This time period includes: (1) public notification of the request within 15 days of receipt; (2) publication of the request in the Federal Register within 60 days after receipt of the request ; (3) opening a docket to facilitate the public comment period of at least 45 days; (4) issuance of the decision to grant or deny the request within 60 days of the end of the comment period; and (5) a 30-day period after US EPA notifies the manufacturer of its decision within which the requester may withdraw the request. If the request is not withdrawn, US EPA will initiate the risk evaluation.

The rule provides that a requester may resubmit any denied request for a risk evaluation.

Next Steps

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US EPA Proposes New Toxic Substances Control Act Fee Rule

By Stephen A. Owens, on March 12, 2018

On February 26, 2018, the US Environmental Protection Agency (US EPA) formally issued its proposed rule to charge new "user fees" under the amended Toxic Substances Control Act (TSCA). The amended TSCA authorizes US EPA to charge fees for a variety of activities under TSCA sections 4, 5 and 6, totaling up to 25% of the overall costs for the agency to conduct these activities. Comments on the proposed fee rule must be submitted to US EPA on or before April 27, 2018.

US EPA expects to collect approximately $20.05 million annually during fiscal years 2019-2021 for the activities for which the new fees will be charged. US EPA has estimated that the overall cost to conduct these activities will be roughly $80.2 million each year.

US EPA will collect fees from chemical manufacturers and processors: (1) who are required to submit information to US EPA pursuant to TSCA section 4 by a test rule, test order or enforceable consent agreement; (2) who, under TSCA section 5, submit a "notification of or information related to intent to manufacture" a new chemical substance (a Premanufacture Notice (PMN) or a Microbial Commercial Activity Notice (MCAN)) or a significant new use of a chemical (a Significant New Use Notice (SNUN)), including submissions related to exemptions; and (3) who manufacture or process a chemical substance that is subject to a risk evaluation under TSCA section 6(b), including a risk evaluation conducted at the request of a manufacturer.

US EPA is proposing user fees as follows:

- For TSCA section 4 activities: (1) a $9,800 fee associated with a test order; (2) a $29,500 fee associated with a test rule; and (3) a $22,800 fee associated with an enforceable consent agreement.
- For TSCA section 5 submissions: (1) a $16,000 fee for each PMN, SNUN and MCAN; and (2) a $4,700 fee for each TSCA exemption (i.e., Low Releases and Low Exposures (LoREX) Exemption, Low Volume Exemption (LVE), Test Marketing Exemption (TME), film article exemption, biotechnology Tier II exemption and biotechnology Experimental Release Application (TERA)).
- For TSCA section 6 risk evaluations: (1) a $1.35 million fee for an EPA-initiated risk evaluation; (2) a $1.3 million fee for a manufacturer-requested risk evaluation for a chemical included in US EPA's TSCA Work Plan; and (3) a $2.6 million fee for a manufacturer-requested risk evaluation for a chemical not included in the TSCA Work Plan.

Lower fees for some activities are proposed for entities that qualify as a small business as follows:

- For TSCA section 4 activities: (1) a $1,950 fee associated with a test order; (2) a $5,900 fee associated with a test rule; and (3) a $4,600 fee associated with an enforceable consent agreement.
- For TSCA section 5 submissions: (1) a $2,800 fee for each PMN, SNUN and MCAN; and (2) a $940 fee for each TSCA exemption (i.e., LoREX, LVE, TME, film article exemption, biotechnology Tier II exemption and TERA).
- For TSCA section 6 risk evaluations: (1) a $270,000 fee for an EPA-initiated risk evaluation; (2) a $1.3 million fee for a manufacturer-requested risk evaluation for a chemical included in US EPA's TSCA Work Plan; and (3) a $2.6 million fee for a manufacturer-requested risk evaluation for a chemical not included in the TSCA Work Plan.

A full, lump sum payment of the fee for a TSCA section 5 activity would be have to be made when the notice (including for an exemption) is submitted to US EPA. The payment relating to information required to be submitted pursuant to a section 4 test order or test rule would be due within 60 days of the effective date of the order or rule. The fee for section 4 information required to be submitted pursuant an enforceable consent agreement would be due within 60 days of when the agreement is signed. For US EPA-initiated chemical risk evaluations, full payment would be due within 60 days of US EPA publishing the final scope of the risk evaluation. For manufacturer-risked risk evaluations, the fee would be due within 30 days after EPA notifies the manufacturer that US EPA has granted the request to conduct the evaluation.

US EPA is proposing that the fees would begin to be "incurred" starting on October 1, 2018, even though the fee rule may not be final by that date. US EPA will not actually start collecting any of the new fees, however, until the final rule is effective. Instead, US EPA intends to "record" actions that "would be expected to trigger payment of fees" and send out invoices for the incurred fees once the rule is final. US EPA would start collecting the fees the day after the final rule is published in the Federal Register.

US EPA would refund any fees paid for a TSCA Section 5 notice whenever the agency determines that the notice or fee was not required (for example, if it is determined that a substance is not subject to TSCA or is already on the TSCA Inventory). US EPA also is proposing to return 75% of the fee to a submitter if a Section 5 notice is withdrawn within 10 business days after its submission.

Failure to pay a fee would be a violation of TSCA and subject to an enforcement action by US EPA, with penalties possible up to the maximum statutory amount for each day until the required fee is paid. Each person subject to a fee would be responsible for such penalties regardless of whether they intended to pay the fee independently, as a joint submitter or through a consortia. Under the proposed rule, each joint submitter and each member of a consortium would be individually responsible for full payment of the fee, and subject to the penalties for non-payment, until the fee is paid in full.

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US EPA Releases Problem Formulation Documents for "First Ten" TSCA Risk Evaluations

By Stephen A. Owens, on June 19, 2018

The US Environmental Protection Agency (US EPA) has formally released "problem formulation" documents for the risk evaluations it is conducting on the "first ten" chemical substances under the amended Toxic Substances Control Act (TSCA). Formal notice of the problem formulation documents was published in the Federal Register on June 11, 2018. Comments on the problem formulations must be submitted to US EPA by July 26, 2018.

US EPA has stated that goal of the problem formulation effort is to produce a "conceptual model and an analysis plan" for each risk evaluation. The conceptual model "describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s) and endpoint(s) that will be addressed in the risk evaluation." The analysis plan "is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs."

The problem formulation documents are intended to "refine" the scoping documents that US EPA issued in June 2017 for the risk evaluations. The "refinements" apply to the conditions of use, hazards, exposures and the potentially exposed and susceptible subpopulations that will be considered in the risk evaluations. Moreover, while each problem formulation is tailored to issues relating to the specific chemical substance covered by the relevant risk evaluation, the problem formulations generally narrow the "conditions of use" that will be covered by the risk evaluations.

In particular, US EPA is removing from the risk evaluations "any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation," such as activities for which the agency has insufficient information to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Additionally, US EPA is generally excluding from the risk evaluations exposure pathways addressed under other US EPA-administered environmental statutes, including specifically the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act. The problem formulation documents explain that US EPA is exercising its discretion under TSCA "to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA."

The problem formulations also identify any conditions of use, hazards or exposure pathways identified in the scope documents that will be included in the risk evaluations but which US EPA "does not expect to further analyze in the risk evaluation." The problem formulations state that US EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and that "[e]ach risk evaluation will be 'fit-for-purpose,' meaning not all conditions of use will warrant the same level of evaluation," including reaching some conclusions "without comprehensive or quantitative risk evaluations."

US EPA has stated that the problem formulation documents are an "interim step" to refine the scope documents prior to publication of the draft risk evaluations. Although US EPA is taking comments on the problem formulation documents, the Agency does not intend to revise them. Instead, US EPA will consider any comments submitted on the documents when developing the draft risk evaluations.

The problem formulation documents can be found on the US EPA website here and in the dockets for the first ten risk evaluations on the www.regulations.gov website as follows:

- 1,4-Dioxane – EPA-HQ-OPPT-2016-0723
- 1-Bromopropane – EPA-HQ-OPPT-2016-0741
- Asbestos – EPA-HQ-OPPT-2016-0736
- Carbon Tetrachloride – EPA-HQ-OPPT-2016-0733
- Cyclic Aliphatic Bromide Cluster (HBCD) – EPA-HQ-OPPT-2016-0735
- Methylene Chloride – EPA-HQ-OPPT-2016-0742
- N-Methylpyrrolidone (NMP) – EPA-HQ-OPPT-2016-0743
- Pigment Violet 29 – EPA-HQ-OPPT-2016-0725
- Trichloroethylene (TCE) – EPA-HQ-OPPT-2016-0737
- Tetrachloroethylene (aka perchloroethylene) – EPA-HQ-OPPT-2016-0732

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SQUIRE PATTON BOGGS

US EPA Issues Final TSCA Mercury Reporting Rule

By Stephen A. Owens, on July 2, 2018

On June 27, 2018, US EPA formally published its final rule under the amended Toxic Substances Control Act (TSCA) to require reporting by persons who manufacture, import or intentionally use mercury and certain "mercury-added products." 83 Fed. Reg. 30054 (June 27, 2018). The final rule is effective on August 27, 2018.

US EPA was required to promulgate the rule by TSCA Section 8(b)(10), which was added by the 2016 amendments to TSCA. Among other things, that section requires that "any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to [US EPA] … including such information as [US EPA] shall determine by rule promulgated not later than two years after June 22, 2016." The information collected by the rule is to be used in the preparation of "an inventory of mercury supply, use and trade" in the US. US EPA was required by TSCA to prepare the first such mercury inventory by April 1, 2017 (which it formally announced on March 29, 2017). The Agency must prepare subsequent inventories by April 1 every three years thereafter beginning in 2020.

US EPA's final mercury reporting rule requires persons "who manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process" to report amounts of mercury above certain amounts that are used in these activities during a designated reporting year. The reporting requirements apply to any person who manufactures or imports 2,500 pounds or more of elemental mercury or 25,000 pounds or more of certain mercury compounds in a specific reporting year, subject to certain exemptions. The final rule also requires such persons to "identify specific mercury compounds, mercury-added products, manufacturing processes and how mercury is used in manufacturing processes, as applicable" as specified in the rule, along with other data outlined in the rule.

The submission deadline for the 2018 reporting year is July 1, 2019. The 2018 reporting period covers January 2018 to December 31, 2018. The final rule states that subsequent reporting years are from January 1 to December 31 at a three-year interval beginning in 2021, with the submission deadlines being July 1 in three-year intervals beginning July 1, 2022. As such, any covered person who meets the reporting volume threshold during calendar year 2018 must report the required information to US EPA by July 1, 2019. Thereafter, any covered person who meets the thresholds during any calendar year during the next three years (2019, 2020 and 2021) must report the information to EPA by July 1, 2022, and so on.

Consistent with TSCA Section 8(b)(10), the final rule contains some exemptions to the reporting requirements. In general, the final rule provides that the reporting requirements do not apply to: persons who (i) do not first manufacture, import or otherwise intentionally use mercury; (ii) who only generate, handle or manage mercury-containing waste; (iii) who only manufacture mercury as an impurity; and (iv) who are engaged in activities involving mercury not with the purpose of obtaining an immediate or eventual commercial advantage. The final rule also provides exemptions from certain specific data elements in the rule for persons who already report comparable information under the TSCA Chemical Data Reporting rule and to the Interstate Mercury Education and Reduction Clearinghouse Mercury-added Products Database.

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SQUIRE PATTON BOGGS

Deadline Nears for US EPA TSCA Nanomaterials Reporting Requirement

By Stephen A. Owens, on July 9, 2018

The August 14, 2018 deadline for reporting under US EPA's nanomaterials reporting rule is rapidly approaching.

US EPA promulgated the rule in January 2017 under Section 8(a) of the Toxic Substances Control Act (TSCA). 82 Fed. Reg. 3641 (Jan. 12, 2017). The rule requires any person that manufactured, imported or processed a covered nanomaterial substance during the three years prior to the rule's effective date to report certain information to US EPA within one year of the effective date.

Although the rule initially was to be effective in May 2017, US EPA extended the effective date until August 14, 2017, making the reporting deadline August 14, 2018. 82 Fed. Reg. 22088 (May 12, 2017). The extension also adjusted the beginning and end dates of the three-year period for which reporting is required.

The rule does not contain a formal definition of nanomaterials. Instead, the rule requires reporting of chemical substances that are solids at 25° Celsius and standard atmospheric pressure; that are manufactured or processed in a form where any particles (including aggregates and agglomerates) are in the size range of 1–100 nanometers (nm) in at least one dimension; and that are manufactured or processed to exhibit one or more "unique and novel properties."

"Unique and novel properties" are defined in the rule to mean "any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form or size." In the preamble to the rule, US EPA explained that a substance is not reportable simply because it contains particles in the size range of 1–100 nm. Instead, the substance "must also demonstrate a size-dependent property different from properties at sizes greater than 100 nm and is a reason the chemical is manufactured or processed in that form or size." The rule also contains exemptions for certain substances, including substances manufactured, imported or processed for R&D purposes, as well as substances that contain less than 1% by weight of any particles, including aggregates and agglomerates, in the size range of 1–100 nm. Additionally, the rule exempts small businesses with sales of less than $11 million per year from the reporting requirement.

Persons who manufactured, imported or processed nanomaterial substances covered by the rule during the three-year period prior to August 14, 2017 must report the following information to US EPA by August 14, 2018 for each such substance:

1. The common or trade name, the specific chemical identity including the correct Chemical Abstracts (CA) Index Name and available Chemical Abstracts Service (CAS) Registry Number and the molecular structure of each chemical substance or mixture.
2. Material characteristics including particle size, morphology and surface modifications.
3. Physical/chemical properties.
4. The maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use or disposal of each chemical substance.
5. The annual production volume for the previous three years before August 14, 2017 and an estimate of the maximum production volume for any consecutive 12-month period during the next two years of production after August 14, 2017.
6. Use information describing the category of each use by function and application, estimates of the amount manufactured or processed for each category of use and estimates of the percentage in the formulation for each use.
7. Detailed information on methods of manufacturing or processing.
8. Exposure information with estimates of the number of individuals exposed in their places of employment, descriptions and duration of the occupational tasks that cause such exposure, descriptions and estimates of any general population or consumer exposures.
9. Release information with estimates of the amounts released, descriptions and duration of the activities that cause such releases, and whether releases are directly to the environment or to control technology.
10. Risk management practices describing protective equipment for individuals, engineering controls, control technologies used, any hazard warning statement, label, safety data sheet, customer training or other information that is provided to any person who is reasonably likely to be exposed to the substance regarding protective equipment or practices for the safe handing, transport, use or disposal of the substance.
11. Existing information concerning the environmental and health effects.

The rule also imposes a "standing one-time reporting requirement" for persons "who intend to manufacture or process a discrete form of a reportable chemical substance" on or after August 14, 2017. Any such person must report the same information above to US EPA, except that for production volume, the party must report the estimated maximum 12-month production volume and the estimated maximum production volume for any consecutive 12-month period during the first three years of production. In general, any such person must report the information to US EPA at least 135 days before manufacturing, importing or processing of the substance. The rule provides, however, that where the person has not formed an intent to manufacture, import or process a discrete form of a reportable chemical substance 135 days before such manufacturing, importing or processing, the information must be provided to US EPA within 30 days of forming the intent. The party cannot manufacture, import or process the substance until it provides the information to US EPA, but it can begin manufacturing, importing or processing the substance at any time thereafter.

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Practice Focus
- Public Finance
- Tax Credit Finance & Community Development
- Environmental, Safety & Health Litigation
- Environmental, Safety & Health
- Healthcare Policy
- Insurance

Education
- Cleveland State University, J.D., 1987, B.A., 1983

Admissions
- Ohio, 1987

Received the highest ranking for legal ability and professional ethics from the Martindale-Hubbell Peer Review Ratings.

Timothy J. Cosgrove is among Ohio's best connected and influential government relations professionals. He combines his experience as director of policy and legislation for former Ohio Governor George V. Voinovich with his training and experience as a lawyer practicing in the legislative counseling, public finance and administrative law areas to serve the needs of corporate, nonprofit and trade association clients in Ohio.

Timothy has been involved in virtually every major policy area in the Ohio General Assembly including tax reform, economic development, healthcare, science and technology and finance. He has also played a role in the advocacy effort of a variety of major Cleveland development initiatives including management of the advocacy efforts in Columbus in support of the financing package for the new Cleveland Browns Stadium, biennial capital budget appropriations and BioEnterprise Cleveland. His participation in Cleveland civic affairs includes having served as chair of the board of trustees of Cleveland State University. He previously served as executive assistant under Mayor George Voinovich.

Timothy's legislative counseling experience includes preparing and drafting legislation and amendments, providing analyses of pending legislation, and presenting testimony and client position papers as well as monitoring and evaluating committee hearings and congressional sessions. He is also heavily involved in government advocacy and government relations. In particular, he assists clients in proactively building relationships with government officials and in developing advocacy strategies that can be integrated into government relations plans. Timothy is experienced in securing appropriations within state operating and capital budgets. He has been recognized by *Cincinnati Magazine* as an Ohio Super Lawyer.

Timothy is a member of the Ohio Lobbying Association and of the Public Affairs Committees of both the Ohio Chamber of Commerce and the Greater Cleveland Partnership.

Timothy is the immediate past chair of the board of directors for the Washington DC-based Northeast Midwest Institute.

REPRESENTATIVE EXPERIENCE

- Securing US$40 million capital budget appropriations for a major sports facility.
- Coordination of US$30 million in capital budget requests for projects in Northeast Ohio.
- Representing a nationally recognized nonprofit hospital system in the passage of medical malpractice reform legislation in Ohio.
- Representing a variety of clients' interests in government contracting issues with various state agencies and regulatory bodies.
- Pursuing agency rule changes on behalf of clients in dealings with the Ohio Department of Taxation, Ohio Department of Development, Ohio Department of Health, Ohio Department of Insurance, Ohio Environmental Protection Agency, Ohio Attorney General and the Office of Budget and Management.

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Practice Focus
- Environmental, Safety & Health
- Chemicals
- Chemicals & Products
- Climate Change & Sustainability
- Environmental, Safety & Health Litigation
- Mergers & Acquisitions

Education
- Case Western Reserve University, J.D., *magna cum laude,* Order of the Coif, executive notes editor, *Case Western Reserve Law Review*, 1999
- Miami University, B.S., 1996

Admissions
- Ohio, 1999
- U.S. Ct. of App., District of Columbia Circuit, 2004
- U.S. Ct. of App., Eighth Circuit, 2013
- U.S. Ct. of App., Fifth Circuit, 2002
- U.S. Ct. of App., Seventh Circuit, 2014
- U.S. Ct. of App., Sixth Circuit, 2007
- U.S. Ct. of App., Third Circuit, 2006
- U.S. Dist. Ct., N. Dist. of Ohio, 2000
- U.S. Dist. Ct., N. Dist. of Texas, 2005
- U.S. Dist. Ct., W. Dist. of Pennsylvania, 2008
- U.S. Supreme Court, 2004

Listed in The Best Lawyers in America, an honor based on an exhaustive peer-review process.

Allen Kacenjar's practice encompasses all areas of environmental law with particular emphases in regulatory development and advocacy, high-stakes environmental litigation, risk management counseling and complex environmental deal-making.

Allen's primary focus is on minimizing his clients' exposure to environmental liabilities, whether through proactive efforts to shape evolving environmental laws, development of business practices, evaluation of transactional risks or aggressive litigation. Through his representation of major corporations, public entities and industry advocacy groups, Allen has obtained substantial experience under all major state and federal environmental laws including the Clean Air Act; Clean Water Act; Resource Conservation and Recovery Act (RCRA); Toxic Substances Control Act (TSCA); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); and Ohio's Voluntary Action Program (VAP).

REPRESENTATIVE EXPERIENCE

Regulatory

- Led internal TSCA compliance investigation for a specialty chemicals company, resulting in voluntary disclosure of identified concerns, negotiation of a consent agreement with minimal penalty and full ability to continue manufacture and use of products.
- Advising manufacturer targeted by EPA MACT residual risk rulemakings of ways to mitigate testing costs, shape ongoing agency rulemaking efforts and minimize risk of overreaching regulatory requirements.
- Developing US climate change strategy for an international steel company including assessment of the preferred regulatory approach, advocacy in support of that approach and submission of comments on numerous rulemakings.
- Guided a major international manufacturer's response to an agency enforcement air permitting initiative, securing the ability to continue operating while avoiding imposition of any penalty and strengthening the company's relationship with its regulators.

- Designing a product redistribution and recycling system for an international chemicals manufacturer with extended attention to RCRA, TSCA and Department of Transportation implications and resolved related RCRA enforcement proceedings.
- Assessed and avoided state and federal enforcement of PSD claims against international manufacturer by securing favorable permit modifications that eliminate compliance risk.
- Securing US Army Corps and Ohio EPA permits necessary to enable development of a major hospital complex on a site with significant wetlands, endangered species and other siting concerns.
- Preparing siting strategy for a proposed offshore wind power generation facility including evaluation of all potential federal and state regulatory impediments.

Transactional

- Provided primary environmental counsel on hundreds of major corporate transactions requiring identification and valuation of environmental, health and safety risks; negotiation of key contractual protections; identification and resolution of permitting concerns; and procurement of environmental insurance.
- Managing international legal and technical team charged with mitigating risk and cost of substantial environmental indemnity claims alleging historic contamination from divested operating and third-party disposal sites.
- Counseling a large municipality regarding the US$100 million remediation and redevelopment of a historic automotive plant into a high-tech business incubator including resolution of intricate RCRA, Ohio VAP, TSCA, political and business concerns.
- Securing significant grant funding to spur remediation of contaminated industrial property in a transaction uniquely structured to eliminate prospective environmental liability despite ongoing enforcement.

Litigation

- Securing a victory before the US Supreme Court in landmark Superfund litigation resulting in the nationwide reassessment of contribution rights (*Cooper v. Aviall,* 543 U.S. 157 (2004)).
- Defended two New York State agencies against citizen suit claims on issues of first impression involving US$500+ million in Clean Water Act funding for the state's largest-ever infrastructure project while simultaneously pursuing affirmative relief against US EPA.
- Secured a rare judicial stay by the Eighth Circuit US Court of Appeals on EPA's regional haze regulation of the taconite industry, thus allowing negotiated resolution to secure additional compliance and timing flexibility.

- Defending a major amusement and water park against environmentalist citizen claims under Clean Water Act while simultaneously working to resolve state enforcement and permitting issues.
- Securing vacatur of the US EPA Boiler MACT rule before the DC Circuit Court of Appeals on behalf of clients threatened with disproportionate regulatory impacts (*NRDC v. EPA,* 489 F.3d 1250 (DC Cir. 2007)).
- Successfully resolving CERCLA litigation involving environmental concerns from a century of operations of a major coke plant in Alabama. Following three separate appeals, the case was before the US District Court for the Western District of Pennsylvania for a new allocation proceeding involving more than a dozen expert witnesses. *Beazer East, Inc. v. The Mead Corporation,* Case No. 91-0408 (W.D. Pa.).
- Defending a manufacturing client from a US$35 million claim regarding a contaminated 116-city-block area in downtown South Bend, Indiana, involving the seminal interpretation of two statutes, four tort claims and complex insurance disputes resulting in two Indiana Supreme Court decisions.

PUBLICATIONS AND SPEAKING ENGAGEMENTS

- "What the New TSCA Reform Legislation Means to You" seminar, presented with the Ohio Chemistry Technology Council, July 2016
- **"**EPA's Clean Power Plan: How Did We Get Here, Where Are We Anyway, and What Happens Next?" presented at the Cleveland Metropolitan Bar Association, May 2016
- "The NAAQS: The Good, the Bad and the Ugly," presented at Ohio State Bar Association Environmental Law Seminar, April 2016
- "Product Stewardship: Who Owns It?" presented at the Roundtable for General Counsel in the Chemical and Performance Materials Industries, March 2015
- "The Clean Power Plan: Challenges & Opportunities," presented to NACWA members, Sept. 2015
- "Corporate Compliance Strategies for an Increasingly Complex World," presented to the Association of Corporate Counsel, Northeast Ohio Chapter, Dec. 2013

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Practice Focus
- Institutional Investors
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Education
- University of Virginia, J.D., 1977
- University of Alabama, A.B., 1974

Admissions
- District of Columbia
- U.S. Court of Appeals for the 5th Circuit
- U.S. Court of Appeals for the 11th Circuit
- U.S. Court of Appeals for the District of Columbia Circuit
- U.S. District Court for the District of Columbia

Clerkship
- Hon. Walter P. Gewin, U.S. Court of Appeals for the 5th Circuit, 1977-1978

W. Caffey Norman's environmental practice focuses on the regulation of hazardous chemicals by the Environmental Protection Agency, the Occupational Safety and Health Administration, the Consumer Product Safety Commission and various state regulatory agencies. He has been particularly active in the subject areas of toxic substances, stratospheric ozone depletion and global warming. For many years, he has developed and successfully implemented strategies to defend products targeted for phase out or use reduction. He has participated in EPA rulemakings to regulate hazardous substances under all the environmental statutes and has initiated legislative and judicial review of a number of EPA regulations. Caffey also represents a number of industry task forces in connection with pesticide registration and the negotiation of test rules and testing consent orders.

Caffey has been actively engaged in OSHA and CPSC regulatory proceedings and related litigation matters. He also has developed substantial expertise in dealing with scientific review boards and non-regulatory organizations such as the International Agency for Research on Cancer, the National Academy of Sciences and the National Toxicology Program.

REPRESENTATIVE EXPERIENCE

- Represent manufacturers of substances targeted in first round of EPA TSCA Chemicals Work Plan assessments.
- Participate in rulemakings and litigation challenging NESHAPs for dry cleaning, solvent cleaning, wood furniture manufacturing and other sources.
- Challenged methylene chloride standard in the US Court of Appeals for the DC Circuit, and negotiated satisfactory settlement with union support.
- Organized coalition of formulators and users and initiated lobbying activities successfully challenging OSHA asbestos standard for removal of ban on aerosol brake cleaners.
- Represented petitioner in litigation to overturn OSHA permissible exposure limit (PEL) standard.

PUBLICATIONS & SPEAKING ENGAGEMENTS

- Speaker, "US EPA and TSCA in the New Administration: What It Means for You," August 2017.
- Speaker, "US EPA Issues TSCA Inventory Reset Rule," July 2017.

- Author, “EPA Implementation of TSCA § 6 Poses Risks for Coatings Industry,” July 2017.
- Author, “US EPA Issues TSCA Risk Evaluation Rule,” July 2017.
- Author, Letters, Toxicology 208: 171-172 (2005), Environmental Forum (May/June 2002), Science (October 18, 1996), Am. J. Ind. Med. 30:508-509 (1996).
- Author, “Risk Assessment,” *The Environmental Law Handbook*, BNA, 1995.

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Practice Focus
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Education
- Vanderbilt University, J.D., editor in chief, *Vanderbilt Law Review*, 1981
- Brown University, B.A., with honors, 1978

Admissions
- Arizona, 1989
- District of Columbia, 1985
- Tennessee, 1981

Received the highest ranking for legal ability and professional ethics from the Martindale-Hubbell Peer Review Ratings.

Recognized by the National Law Journal as an Energy & Environmental Trailblazer.

Steve Owens focuses his practice on environmental, safety and health issues and has been recognized by the *National Law Journal* as an "Energy and Environmental Trailblazer." From 2009 until November 30, 2011, Steve served as the United States Environmental Protection Agency's Assistant Administrator, Office of Chemical Safety & Pollution Prevention. Appointed by President Obama and unanimously confirmed by the US Senate, Steve was responsible for managing US regulatory and scientific programs on pesticides and industrial chemicals, including nanotechnology and biotechnology under the Toxic Substances Control Act (TSCA); Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Federal Food, Drug and Cosmetic Act (FFDCA); Food Quality Protection Act (FQPA); and other statutes. As Assistant Administrator, Steve was also responsible for many of US EPA's collaborative pollution prevention programs and the implementation of the federal Pollution Prevention Act (PPA).

Prior to joining the EPA, Steve served from 2003 to 2009 as Director of the Arizona Department of Environmental Quality. Steve directed agency operations on matters including air quality, water quality, hazardous and solid waste, clean and renewable energy, climate change and children's environmental health. Steve also served as chair of the Water Infrastructure Finance Authority of Arizona.

From 1988 to 2003, Steve was in private practice in Phoenix, representing clients on the full range of federal and state environmental laws, including the federal Comprehensive Environmental Response, Compensation & Liability Act (CERCLA), Resource Conservation & Recovery Act (RCRA), Clean Air Act (CAA), Clean Water Act (CWA), and Emergency Planning & Community Right to Know Act (EPCRA), and the Arizona Water Quality Assurance Revolving Fund (WQARF) and Arizona Aquifer Protection Permit (APP) laws. Steve began his legal career in 1982 as Counsel to the Subcommittee on Investigations and Oversight of the US House Committee on Science and Technology, and later as Chief Counsel and Tennessee State Director for US Senator Al Gore.

During 2012-2014, Steve was co-chair of Phoenix Mayor Greg Stanton's Sustainability Advisory Committee and also was a member of the Advisory Board of Arizona State University's Sandra Day O'Connor

College of Law's Center for Law, Science and Innovation. Steve also has served as an expert technical reviewer for the National Academy of Sciences. He served as co-chair of the Western Climate Initiative (2007-2008), on the Executive Committee of The Climate Registry (2007-2009), chair of the Arizona Climate Change Advisory Group (2005-2006), chair of the Western Regional Air Partnership (2003-2009) and a member of EPA's Clean Air Act Advisory Committee (1993-2004). By appointment of President Clinton, Steve was a member of the Joint Public Advisory Committee of the North American Commission on Environmental Cooperation (1999-2002), which addresses environmental issues under NAFTA. He was also co-chair of the Arizona-Mexico Commission Environment Committee, which addressed environmental issues on the Arizona-Mexico border. From 2006 to 2009 Steve was an officer and president of the Environmental Council of the States.

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- Energy & Natural Resources
- Environmental, Safety & Health Litigation
- Metals, Mining & Natural Resources

Education
- The Ohio State University, J.D., managing editor, *Ohio State Law Journal*, 1997
- Stanford University, B.A., 1992

Admissions
- Ohio, 1997
- U.S. Dist. Ct., N. Dist. of Ohio
- U.S. Dist. Ct., S. Dist. of Ohio

Kendra Sherman advises and counsels public and private companies, real estate developers and municipal clients on environmental compliance, due diligence, transactional and permitting issues and appeals, environmental litigation and defense of environmental tort claims and citizen suit challenges.

Kendra's practice encompasses all areas of environmental law. She represents a broad spectrum of clients, including metals, mining, iron and steel, and chemical companies, waste management and environmental services companies (including solid waste landfills and construction and demolition debris facilities), real estate developers throughout the US and public law clients, including cities and villages. Kendra defends clients in federal and state enforcement actions related to air, water quality, wetlands and solid and hazardous waste matters, and represents clients in appeals and challenges related to Clean Air Act Title V permits and National Pollutant Discharge Elimination System (NPDES) wastewater permits. Kendra has appeared before a wide range of federal and state courts and administrative tribunals in Ohio, West Virginia, Indiana, Illinois, Pennsylvania, Georgia and Washington DC.

Kendra also counsels sellers, lenders, investors and real estate developers on environmental due diligence and other issues in complex commercial and real estate transactions, including brownfields redevelopment and Ohio's Voluntary Action Program, project siting and permitting, and impacts to jurisdictional waters, streams and isolated wetlands. She also has experience in advising clients on shale gas development in the Marcellus and Utica shale gas regions of the US.

In addition, Kendra counsels clients throughout the US on compliance and enforcement matters related to Proposition 65, California's clear and reasonable warning regulations.

Kendra is the Attorney Mentoring Coordinator for the Columbus office. She has also served on the firmwide Inclusion & Diversity Committee, the Columbus Office Hiring Committee and the firmwide Associate Training and Mentoring Taskforce.

Among her many *pro bono* activities, Kendra co-founded Squire Patton Boggs' Dispute Resolution and Youth Program, a community service program aimed at teaching dispute resolution skills to inner city youth in Columbus in collaboration with The Ohio State University College of Law. Kendra also received the Volunteer Lawyer of the Year Award from the National Center for Adoption Law & Policy at Capital University Law School for her community service efforts in the field of adoption law.

AWARDS AND DISTINCTIONS

- Recognized in *The Best Lawyers in America* for Environmental Litigation
- Recognized in *Columbus CEO* magazine's Top Lawyers list in the area of Environmental Health & Safety law (2016) and Environmental/Natural Resources law (2015)
- Recognized for five years as a Rising Star in *Ohio Super Lawyers*, a distinction that recognizes lawyers under the age of 40 or those in practice for 10 years or less

MEMBERSHIPS AND AFFILIATIONS

- Member of the Ohio State Bar Association, Environmental Law Committee
- Member of the Columbus Bar Association, Environmental Law Committee
- Member of the Ohio Women's Bar Association, Energy and Environment Subcommittee

REPRESENTATIVE EXPERIENCE

- Representing iron and steel, chemicals and landfill clients in a wide range of environmental, litigation, compliance, permitting, and state and federal enforcement matters and appeals for facilities located in Ohio, West Virginia, Indiana, Pennsylvania, New York, Minnesota, South Carolina and Texas.
- Counseling real estate developers throughout the US on environmental issues and due diligence for commercial and residential property development, including drafting contract provisions, reps and warranties, indemnities and negotiating with lawyers, sellers and lenders on transactional issues.
- Counseling one of the country's leading developers of large, complex, mixed-use projects on property redevelopment matters related to environmental covenants and Ohio's Voluntary Action Program.
- Representing landfill clients in the defense of environmental tort (including nuisance) claims associated with alleged odors and emissions.
- Representing clients in numerous Title V air permit appeals in administrative tribunals in Ohio, Indiana and Pennsylvania and successfully resolving the appeals following complex permitting negotiations with environmental regulators in those states.
- Representing corporations, municipalities and villages in Ohio, Indiana, Pennsylvania and West Virginia in administrative appeals involving their NPDES permits, solid waste permits and hazardous waste closure plans, and extensive permit negotiations with environmental regulators in those states in the successful settlement and dismissal of the appeals.

- Representing several solid waste landfills and other environmental services companies in Ohio in permitting and enforcement matters, including counseling on disclosure statements and necessary approvals from the Ohio Attorney General's Environmental Background Investigations Unit.
- Representing clients in matters related to California's Proposition 65 law and regulations and advising clients on compliance and enforcement issues related to consumer product warning, labeling and packaging as it pertains to Proposition 65.
- Representing real estate developers and other clients in jurisdictional waters and wetlands permitting matters, including successfully obtaining a remand of a jurisdictional waters determination by the Corps of Engineers and defending clients in jurisdictional waters enforcement matters.
- Advising clients in evaluating shale gas reserves in Pennsylvania, West Virginia and Ohio and negotiating leases associated with shale gas development.
- Representing an ethanol production plant in defense of its air and water permits in appeals filed by a citizen group and successfully resolving all issues in the appeals.
- Representing municipal clients in federal and state court and in administrative hearings in matters involving extraterritorial utility service issues and water and wastewater management planning, utility service and annexation issues.
- Prosecuting a Resource Conservation and Recovery Act (RCRA) citizen suit on behalf of a lender client, resulting in a permanent injunction requiring petroleum contamination cleanup of the lender's property and award of our attorney fees.
- Representing a municipality in the defense of a Clean Water Act citizen suit filed regarding the city's combined sewer overflows resulting in a dismissal of the citizen suit.
- Representing an independent power producer in connection with obtaining a certificate of environmental compatibility and public need from the Ohio Power Siting Board for construction of an 850 MW combined cycle natural gas fired electric generating facility in Ohio and related environmental permits.
- Representing former bituminous coal mining facilities and coal refuse disposal areas in Pennsylvania in acid mine drainage permitting and management matters.
- Counseling and defending companies throughout the US and the UK in compliance enforcement and labeling and regulatory matters concerning Proposition 65, California's clear and reasonable warning regulations.

SQUIRE PATTON BOGGS

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Practice Focus
- Environmental, Safety & Health
- Chemicals
- Chemicals & Products
- Industrial Products
- Energy & Natural Resources
- Environmental, Safety & Health Litigation

Education
- The University of Akron, J.D., 1981
- Bowling Green State University, B.A., 1978

Admissions
- Ohio, 1981
- U.S. Supreme Court, 2016
- U.S. Ct. of App., Sixth Circuit, 1982
- U.S. Dist. Ct., N. Dist. of Ohio, 1982
- U.S. Dist. Ct., S. Dist. of Ohio, 1982

Recognized as one of the 2018 Legal Leaders: Midwest by Martindale-Hubbell

Listed in The Best Lawyers in America 2018, an honor based on an exhaustive peer-review process

Recognized by Chambers USA as a Leading Individual for natural resources and environmental matters

Karen Winters leads our global Environmental, Safety & Health Practice Group. She has an established reputation for successfully assisting clients in the management of large-scale environmental liability and compliance issues, providing them with strategic counseling; defense of federal and state enforcement proceedings; defense of environmental tort claims including public nuisance claims; and advancement and defense of claims for cost recovery. She is experienced in complex project siting and development (including endangered species and impacts to wetlands and jurisdictional waters), and public advocacy. Her clients are primarily in the chemicals, energy and natural resources, diversified industrials, iron and steel and environmental services industries.

Prior to joining our firm, Karen worked for five and a half years in the Office of the Ohio Attorney General as an Assistant Attorney General, including Assistant Chief of the Consumer Fraud Division, member of the Environmental Enforcement Division, member of the Federal Litigation Division and member of the Chief Counsel's staff.

Karen is a member of the American Bar Association's Section on Environment, Energy and Resources; the Ohio State Bar Association's Environmental Law Committee and the Columbus Bar Association's Environmental Law Committee. She is also a member of the American Iron and Steel Institute's Environment Committee, the Ohio Chamber of Commerce's Energy and Environment Committee (and serves on its Executive Committee), the Ohio Manufacturers Association's Environment Committee and the Ohio Chemistry Technology Council's Regulatory Committee.

Karen has received a number of recognitions and distinctions. She is recognized as a Top Rated Lawyer in *The American Lawyer's* "Women Lawyers in the Law." She has been listed in *Chambers USA – America's Leading Business Lawyers* in the area of environmental law each year since 2005. She has also been selected by her peers for inclusion in *The Best Lawyers in America* each year since 2006 and has been included in

Thomson Reuters' list of Ohio Super Lawyers, the top 5% of lawyers in Ohio, each year since 2004. Karen is AV-Preeminent rated by Martindale-Hubbell. She has been consistently identified by *Columbus Monthly* as one of the top 25 women lawyers in Columbus and was recently featured in *Columbus CEO* magazine as one of the top lawyers in Central Ohio.

Karen is a member of the Board of Trustees of the Columbus Bar Foundation, whose mission is to promote the understanding of the law, the role of the legal profession and access to justice. Karen was a member of the Governing Board of Trustees of the YWCA Columbus (2012-17) whose mission is to eliminate racism and empower women.

REPRESENTATIVE EXPERIENCE

- Successfully resolving claims in bankruptcy by the US and the states of Oklahoma, Kansas, Illinois, Michigan and Ohio under CERCLA against a debtor and its affiliates through the establishment of a custodial trust to take ownership of and remedial responsibility for 13 sites in five states through the appointment of a qualified trustee and funding of the custodial trust in the amount of approximately US$17 million.
- Counseling a manufacturer with respect to compliance with the requirements of federal laws and the laws of the states regarding product labeling, hazardous materials transport and waste management at end of product life under such programs as, *inter alia*, the Hazardous Substances Act, Hazardous Materials Transportation Act, Resource Conservation & Recovery Act and various state analogs associated with entry into the US market.
- Representing an environmental services company in the defense of environmental tort claims, including public nuisance claims regarding associated odors and emissions from a landfill.
- Representing a major oil refiner in connection with the decades' long implementation of an RCRA 3008(h) Administrative Order on Consent issued by US EPA for clean-up of historic contamination associated with the operation of a former refinery. Counsel included assistance with contingency arrangements for an adjacent municipal water supply, as well as ultimate relocation of that water supply through a unique co-funding proposal with the Ohio Water Development Authority.
- Representing a wind energy developer in connection with obtaining a certificate of environmental compatibility and public need from the Ohio Power Siting Board for a 200 MW wind-powered electric generating facility comprised of 112 turbines and a 138 kv transmission line to connect the facility to the regional grid. The facility is intended for use by utilities that will be required to meet the Ohio Alternative Energy Portfolio Standard enacted with passage of SB 221 and signed by Ohio's governor, which requires that, by 2025, at least 25% of the electricity sold in Ohio must be supplied by alternative energy resources.

- Representing an independent power producer in connection with obtaining a certificate of environmental compatibility and public need from the Ohio Power Siting Board for construction of an 850 MW combined cycle natural gas-fired electric generating facility in Southwest Ohio and related environmental permits.
- Representing a private developer in connection with obtaining one of Ohio's first permits for construction of a new solid waste disposal facility pursuant to its best available technology standards for the siting, design, construction and operation of municipal solid waste landfills, promulgated pursuant to Uncodified Section 7 of Am. Sub. HB 592, as revised to meet US EPA's standards under Subtitle D of the Resource Conservation and Recovery Act, and the defense of citizen challenges until then.
- Representing a developer in connection with obtaining one of the first covenants not to sue under Ohio's Voluntary Action Program, which was designed to stimulate brownfields redevelopment in Ohio.
- Representing a host of steel companies on a variety of legislative and regulatory matters including legislation and rules to implement Ohio's Voluntary Action Program and steel-specific siting, design and operational standards for landfills disposing of residual waste from the iron- and steel-making processes.