

TSCA 2019 Outlook

January 9, 2019

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(View the slides via webinar, and hear the sound via phone)



Thomas C. “Tom” Berger



Tom Berger has a chemical engineering background and is a partner at Keller and Heckman. His practice focuses on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and its international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. Mr. Berger also counsels trade association clients on various matters, including environmental, and product disparagement and defense issues. Mr. Berger has been heavily involved in “reformed” TSCA, EPA’s Chemical Data Reporting (CDR) rule, TSCA “Work Plan Chemicals,” and the TSCA Inventory “reset.”



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James G. Votaw



James Votaw is an environmental law partner at Keller and Heckman focusing on regulation of new and existing conventional and nanoscale chemicals under the Toxic Substances Control Act (TSCA) and pesticides and pesticidal devices under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Among other things, James obtains pre-market approvals, negotiates testing orders, and defends enforcement actions under these statutes.



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Javaneh Nekoomaram



Javaneh Nekoomaram is an associate in the environmental and workplace safety and health (OSHA) practice groups at Keller and Heckman.

Ms. Nekoomaram practices in all areas of environmental law as well as occupational health and safety law, and chemical control law. She routinely advises clients on a broad range of environmental health and safety compliance issues.



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- Federal government shutdown impact
- New chemicals – continued evolution of premanufacture review and risk management practices
- Inventory “reset” – effective date and implications
- Potential Chemical Data Reporting (CDR) rule amendments
- Next batches of risk evaluations and risk management rules for existing chemicals
- Selection and prioritization of 40 existing chemicals for risk evaluation
- Plan for retrospective review of certain existing CBI claims
- EPA PFAS Management plan, proposed SNUR for PFAS chemicals
- Upcoming federal court decisions on TSCA framework rules

Central Themes/Issues for 2019



- Section 5 PMN/SNUR pipeline/delay and process evolution
- Inventory reset implementation
- CDR upgrade
- Agency ability/inability to meet LCSEA and industry deadlines
- Section 6 prioritization and risk evaluation continuation
- Continued CBI assertion/handling issues
- **NGO litigation**

Principal Sections of TSCA



- Section 3 – Definitions
- Section 4 – Test rules/orders
- Section 5 – Premanufacture Notification
- Section 6 – Unreasonable Risk Regulation
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
- Section 14 – Confidentiality
- Sections 15 and 16 – Penalties
- Section 18 – Preemption

United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,
the fourth day of January, two thousand and sixteen*

An Act

To modernize the Toxic Substances Control Act, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Frank R. Lautenberg Chemical Safety for the 21st Century Act”.

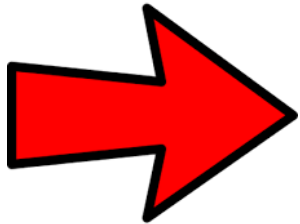
(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

2018–19 Partial Government Shutdown



- Commenced midnight 12/21/2018 for all non-essential Agency functions
 - we are 18 days in...
- EPA has contingency plan (12/31/2018) but no TSCA-specific plan
 - Of 981 OCSPP personell, only 24 are excepted/exempted
- Will impact each TSCA activity/section differently
- Could have significant impact (and spur litigation) for required §6 actions
- Section 5 – in, *e.g.*, 2013 EPA used its §5(c) review period extension authority for PMNs, LVEs, SNUNs, MCANs, *etc.*
 - Duration of extension = length of shutdown
 - If §5 notice submitted during shutdown, RP did not begin until operations resumed
 - FR notice issued after operations resumed

Section 5 - LCSA



“A” risk determination
Presents...

NEW

Must act under §5(f): Shall -

- Issue proposed §6(a) rule, or
- Issue *proposed* 5(f) order; ~~or~~
- ~~Apply for an injunction~~

“B” risk determination

- *Insufficient info, **and** or*
- *May present*

Must act as required by §5(e): ~~May~~

- Shall issue §5(e) order ... to the extent necessary to protect against unreasonable risk; ~~or if no order~~
- ~~Must apply for an injunction~~

“C” risk determination
Not likely to present

- Submitter may begin manufacture or import
- Does not have to wait full 90 days

- Has/will evolve in terms of (1) data needed and (2) regulatory approach
 - **Data Required**
 - Complete halt in approvals → upfront 90-day inhalation study → lung toxicity project (tiered testing, particle size and biosolubility testing “offramps”)
 - **Approach**
 - Current approach = protracted “non-order SNUR” unless toxicity testing required, in which case traditional 5(e) order/SNUR to be used

■ 2019 Outlook

- Improved test method clarity?
- Litigation over non-order SNURs?
- Finalization(?) of:
 - 07/2016 General SNUR provision amendments
 - HAZCOM, water release, etc.
 - 10/2014 NPE / ethoxylates SNUR
 - 01/2015 TDI SNUR
 - 05/2015 PFAS SNUR
 - 06/2018 Asbestos SNUR

Section 8(b) Inventory “Reset” Rule



- August 11, 2017: EPA publishes final rule to “reset” TSCA Inventory
 - 82 Fed. Reg. 37,520
- Companies required to report substances manufactured/imported for non-exempt purposes in 10-year period (“lookback period” (LBP))
 - LBP = June 21, 2006 to June 21, 2016
 - Mandatory for manufacturers and importers (2/7/18), voluntary for processors (10/5/18)
 - Notice of Activity (NOA) “Form A” used
 - Called “retrospective” reporting

Reset Rule (cont.)



- Based on NOA Form As, **in early 2019** EPA will publish revised Inventory subdivided into separate lists of “active” and “inactive” substances
- If and when designated “inactive,” substance cannot be manufactured, imported, or processed unless EPA notified in advance (“forward-looking reporting”) (NOA Form B)
 - Substance not formally designated “inactive” until 90 days after EPA identifies substance as such
- Total Inventory: ~86,000 substances
 - Active: ~38,000 substances
 - ~31,000 “public” substances
 - ~7,000 CBI substances
- This leaves **~48,000 substances** as inactive...

When Must NOA “Form B” Be Submitted?



- Before actual, but not more than 90 days prior to anticipated date of manufacture, import, or processing of inactive substance
- Also may be submitted during 90-day period between identification and effective date for inactive designation, by person (a) currently manufacturing or processing or (b) who anticipates doing so within 90 days following submission

What If You Did Not Submit a Required Form A?



- Could submit late NOA Form A (and presumably use EPA “Audit Policy”)
 - Even if reported by one or more other companies and now “active”
 - Duty to correct?
- Submit Form B as otherwise required
 - Would not eliminate liability for failure to file Form A

What If I Handle “Inactive” Substance?



- Unlike substances that are not on the Inventory (see §15(2), processors are strictly liable for handling inactive substances once so designated
- Prudent to request “active” assurances from suppliers
 - Also may wish to seek indemnification
- *Also . . . remember that polymer exemption reports are due Jan. 31*

- TSCA Section 8(a)
 - Manufacturers must report processing and use information covering previous four years
 - Covers chemicals in commerce above certain production volumes
 - 25,000 lbs or more (generally)
 - 2,500 lbs or more (substances subject to certain TSCA actions)
- Fall 2018 regulatory agenda
 - Proposed rule: Dec. 2018
 - Final rule: Oct. 2019
- Amendments intended to align with LCSEA

Section 6 Risk Evaluations



- Section 6(b) draft risk evaluations for first ten chemicals
 - Pigment Violet 29 released; comments due Jan. 14th
 - Nine other draft risk evaluations to be released
 - Andrew Wheeler letter to Senator Carper:
 - Comment period for draft risk evaluations will be at least 60 days
 - Efforts will be made to stagger their release
 - Final risk evaluations must be completed by Dec. 2019
- Section 6(a) risk evaluations
 - Methylene chloride and NMP in commercial and consumer paint and coating removal
 - TCE use in vapor degreasing
 - TCE in aerosol degreasing and spot cleaning at dry cleaning facilities

Chemicals Up for Prioritization



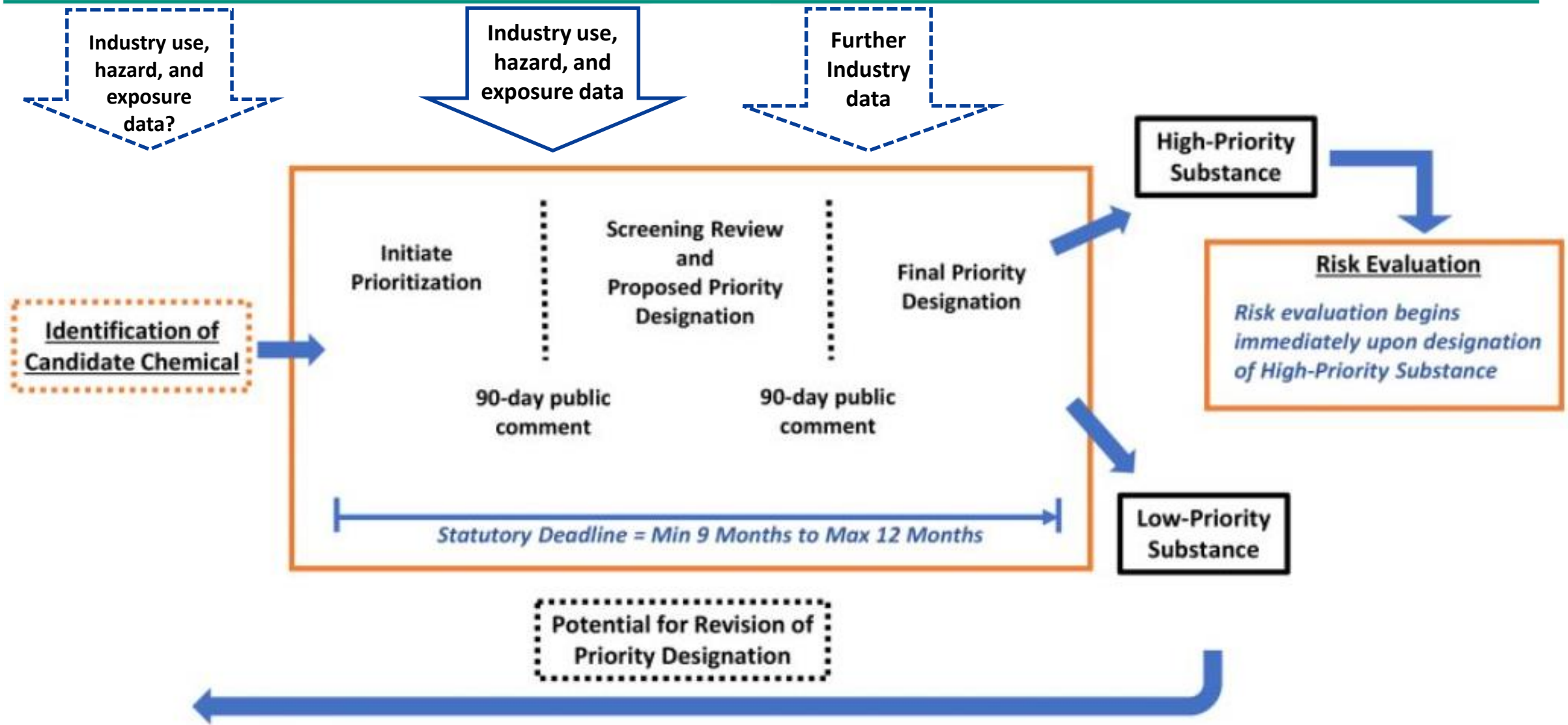
- EPA opened dockets for TSCA Work Plan chemicals
- Dec. 2018 – Mar. 2019: EPA to announce selection of 20 high and 20 low priority candidate chemicals for prioritization.
 - Selection of chemicals based on EPA Working Approach for Prioritization
- Final designations must be made by Dec. 2019

Chemicals Up for Prioritization



- Process/Timeline
 - Fed Reg Notice
 - 90-day commenting period
 - EPA can extend up to three months
 - Screening review and proposed priority designation
 - Fed Reg Notice – proposed designation
 - 90-day commenting period
 - Fed Reg Notice – final designation
 - In no fewer than nine months or longer than one year following initiation of prioritization (publishing initial Fed Reg notice)

Prioritization Process



Retrospective Review of CBI Claims



- TSCA Section 8(b)
- Must issue final rule within one year of compiling active substances on TSCA inventory
- Plan to review CBI claims to protect specific chemical identities on confidential portion of inventory
 - EPA required to assign unique identifiers to confidential chemical identities
- Proposed rule expected Jan. 2019
- EPA to provide Congress with report on how Agency is complying with CBI provisions of LCSEA within 180 days

Perfluoroalkyl Substances (PFAS)



- **EPA's PFAS National Leadership Summit (2018)**
 - Develop PFAS National Management Plan
 - ✓ Develop toxicity guideline (RfD) values for GenX and PFBS
 - ✓ Groundwater cleanup recommendations for PFOA and PFOS
 - Evaluate: Set maximum contaminant level (MCL) for PFOA and PFOS?
 - Propose PFOA and PFOS as “hazardous substances” (Superfund/Clean Water Act)
 - Interagency research coordination
- **ATSDR Minimum Risk levels: PFOA, PFOS, PFHxS, PFNA (2018)**
- **Issue supplemental proposed SNUR for PFAS (2019)**
 - Respond to comments on 2015 PFAS proposed SNUR (lists of ongoing uses)
 - 2015: Bar commencing uses of long-chain perfluoroalkyl carboxylates (articles too)
 - 2015: Bar perfluoroalkyl sulfonate (PFAS) in carpets
 - *Identify/disclose ongoing uses/imports (and in articles)*
- **2019: Much PFAS fed/state regulatory activity outside of TSCA**

TSCA Litigation: Prioritization and Risk Evaluation Rules



Key issue: Extent of EPA’s flexibility to consider less than all foreseeable uses in risk evaluation (“conditions of use”)

Briefing Status (U.S. Ct. App. 9 th Cir)	
Aug. '17	Petition for review filed, <i>Safer Chemicals Health Families v. EPA</i>
Apr. 16	NGO Petitioners filed their opening brief (2018)
Apr. 24	Healthcare NGOs filed amicus brief in support of Petitioners
Aug. 6	EPA Respondents brief filed
Aug. 9	PETA amicus brief in support of EPA
Sep. 19	Intervenors brief (Industry) filed
Nov. 9	NGO Petitioners reply brief filed
2019	Oral argument
?	Decision

TSCA Litigation: TSCA Inventory Reset Rule



Key issue: Whether chemical identity CBI claims are preserved for “inactive” substances (not notified as active in 2018)

Briefing Status (U.S. Ct. App. 2 nd Cir)	
Sep. '17	Petition for review filed, <i>Environmental Defense Fund v. EPA</i>
Mar. 6	NGO Petitioners' opening brief filed
May 21	EPA brief filed
May 31	Intervenors brief (Industry) filed
Jun. 14	NGO Petitioners' reply brief filed
Oct. 12	Oral argument
2019	Decision



Please join us at 1:00 PM Eastern U.S.
Wednesday, January 16, 2019
www.khlaw.com/OSHA3030



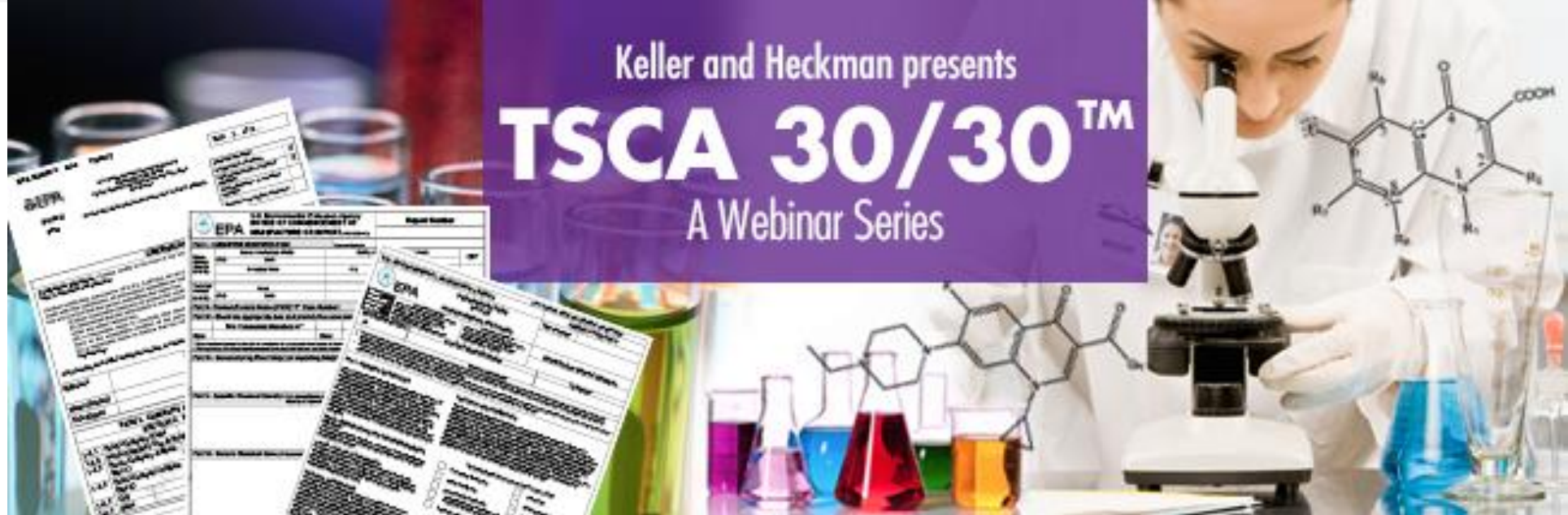
Please join us at 1:00 PM Eastern U.S.
Wednesday, February 13, 2019
www.khlaw.com/TSCA-3030



Please join us at 1:35 PM Eastern U.S.
Wednesday, January 9, 2019
www.khlaw.com/REACH-3030



Next session to be scheduled
www.khlaw.com/FIFRA-3030



The Next TSCA 30/30:
Wednesday, February 13, 2019

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