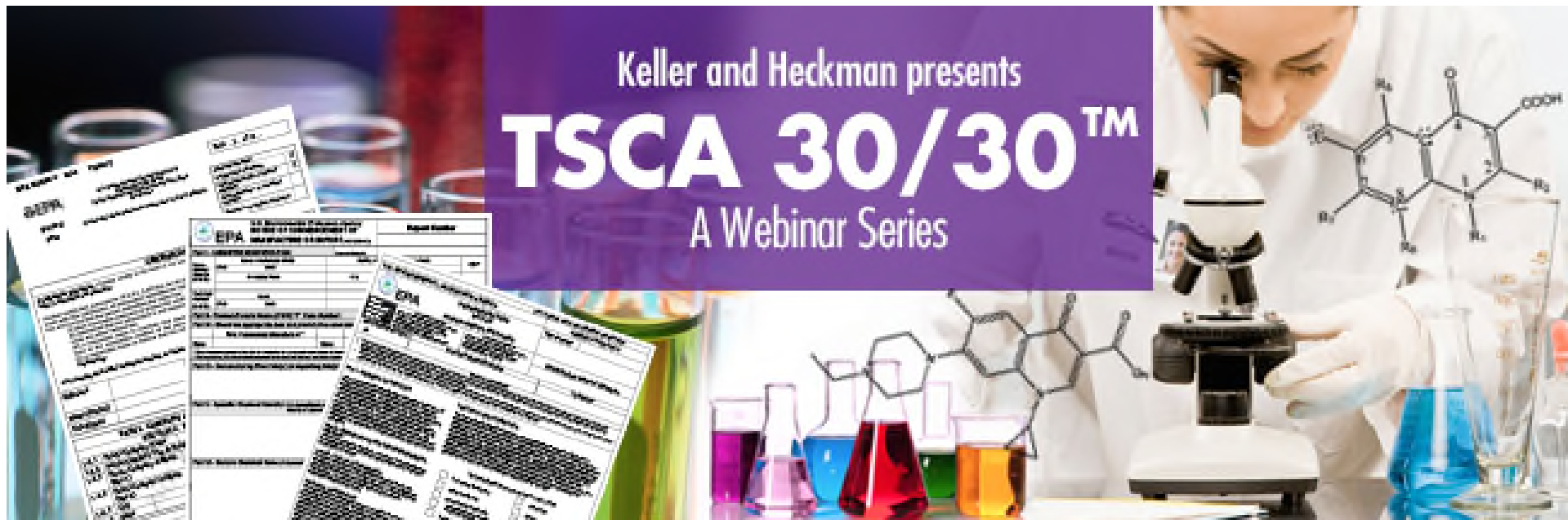


Substantiating Confidential Business Information

October 11, 2017

KH[®] KELLER AND HECKMAN LLP
SERVING BUSINESS THROUGH LAW AND SCIENCE[®]



Please Don't Forget to Dial-In:

Conferencing Number: (800) 768-2983

Access Code: 434 4318

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

David G. Sarvadi, Esq.



Mr. Sarvadi practices in the areas of occupational health and safety, toxic substance management, pesticide regulation, and product safety.

Mr. Sarvadi represents clients before a variety of federal and state enforcement agencies in legal proceedings involving OSHA citations, EPA Notice of Violations, TSCA consent orders, CPSC Notices, FIFRA Stop Sale Use and Removal Orders, and EEOC Charges of Discrimination. He works with clients in developing, reviewing, and auditing compliance programs in all of these areas, and in obtaining agency rulings on proposed or novel activities and questions, seeking interpretations of regulations as they apply to specific sets of facts. He has been counsel to the National Coalition on Ergonomics from its inception.



He has a background in occupational safety and health, having worked as an industrial hygienist for more than 15 years and became a Certified Industrial Hygienist in 1978, a designation he held until he voluntarily relinquished it in 2010. Prior to becoming an attorney, he managed a corporate industrial hygiene program for a Fortune 500 company. Mr. Sarvadi was selected by the National Academy of Sciences to participate in a panel of the Institute of Medicine that was asked to review a NIOSH study on the use of respirators. He was asked to participate because of his expertise in law and industrial hygiene.

Sarvadi@khlaw.com • 202.434.4249

Adrienne M. Timmel, Esq.



Adrienne Timmel specializes in regulatory compliance and enforcement matters under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Ms. Timmel assists clients in obtaining pre-manufacture approval of chemicals under TSCA and pesticide registrations under FIFRA in the U.S. and under comparable statutes in international markets. She also advises clients on compliance with the EPA fuels registration and regulation programs, product labeling, and hazard communication. Her work has included audits under EPA's "Audit Policy" and EPA settlement negotiations. Ms. Timmel represents individual companies as well as trade associations and has also counseled trade association clients on antitrust matters.



Timmel@khlaw.com • 202.434.4164

Agenda



- ✓ When to submit substantiation – “retrospective” versus “upfront”
- ✓ What to substantiate, including grouping claims, follow-up filings and § 14(c)(2) exemptions
- ✓ The claims review and appeals process
- ✓ Status of FOIA request for CDR data on initial 10 chemicals EPA selected for risk evaluation
- ✓ The need for notice and comment rulemaking to resolve questions, get practical input from the regulated community and update the existing TSCA CBI regulations

TSCA Reform & Impact on CBI



- New § 14 completely replaces old §14
- More detailed CBI procedures and timelines and **required claim substantiation** except for CBI described in § 14(c)(2)
- EPA 90-day review:
 - 100% of all chemical identity CBI claims
 - At least 25% of all other CBI claims
- 82 Fed. Reg. 6,522 (Jan. 19, 2017) Notice of Interpretation
 - **Upfront substantiation** – required for all non-exempt CBI claims beginning March 21, 2017
 - **Retrospective substantiation** – due by October 19, 2017 for all non-exempt CBI claims submitted between June 22, 2016 and March 20, 2017

Substantiation Templates & Guidance



- Available at <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations>
- 3 Templates: Generic, Section 5, CDR
 - Some detailed explanations required
 - Some box-checking
 - Grouping of similar CBI allowed
 - Can claim substantiation CBI
- List of section 5 and CDR data elements EPA considers exempt from substantiation under § 14(c)(2)

Tips and Tricks



- For follow-up submissions (e.g., support document or amendment to previously-filed PMN), cumulative substantiation not required
- Include cover note explaining what is and is not substantiated and why
- Include copy of previous substantiation, where applicable, rather than simply referencing it
- Contractors will likely review retrospective substantiations, so make them as easy as possible to review
- EPA not currently requiring substantiations for withdrawn filings
- Where accession number is provided, EPA suggests substantiating the underlying chemical identity

Deficiencies and Denials



- 30-days' notice generally required prior to disclosure
- Can appeal denial in U.S. district court
- If retrospective substantiation is not received by Oct. 19th, then EPA will provide claimant a “final opportunity” to substantiate in 30 days
- Should presume EPA will not provide another opportunity to cure any deficiencies

→ CBI claims should be carefully and timely substantiated!

FOIA Requests



- § 14(f)(2): CBI claims submitted any time (including *before* June 22, 2016) must also be substantiated when EPA receives a FOIA request
 - § 14(c)(2) substantiation exemptions do not apply
- NGOs FOIAed 2016 CDR data on initial 10 substances selected for risk evaluation
- § 14(d)(7): CBI may be disclosed “if the Administrator determines that disclosure is relevant in a proceeding under this chapter, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding.”
 - CBI data requested on this basis as well
- Many companies withdrew CBI claims rather than substantiate
- TSCA CBI office forwarded recommendations to OGC and expects response to issue within 60 days

Need for Rulemaking

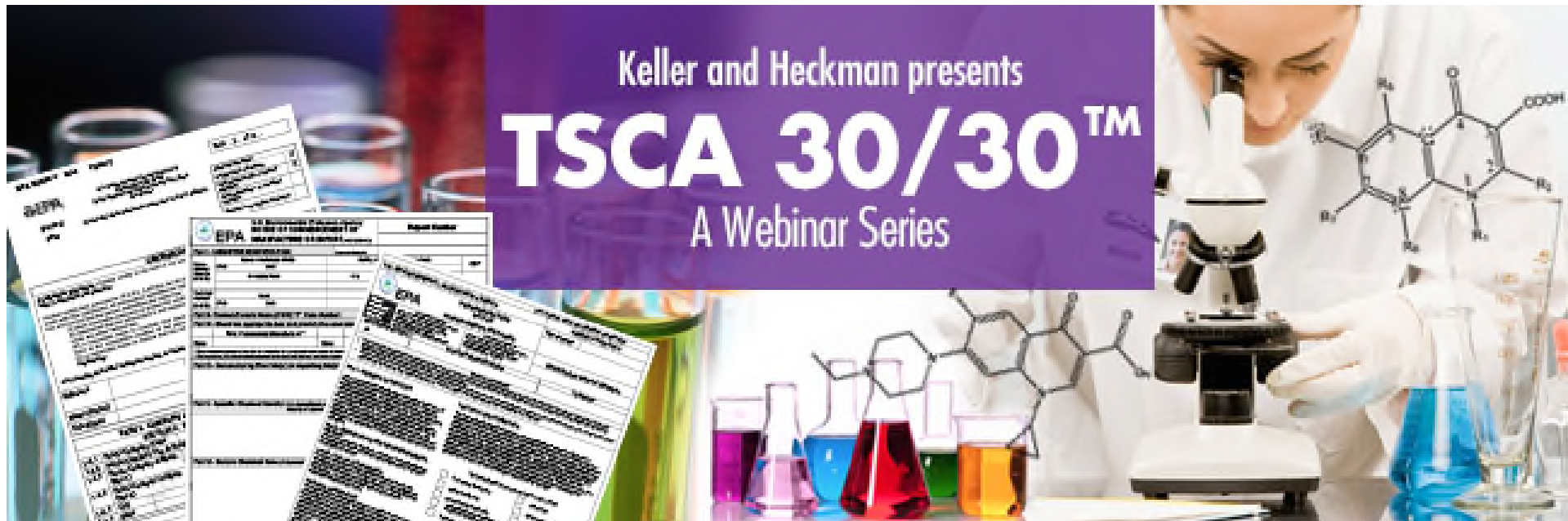


- There continues to be a need for notice and comment rulemaking
 - To resolve outstanding questions
 - Scope of substantiation exemptions, e.g., marketing/sales information
 - Which CBI questions must be answered for particular information classes or filings
 - To update existing TSCA CBI regulations
 - To develop administrative process for resolving substantiation questions or deficiencies
 - To get practical input from regulated community
- Can petition for rulemaking under the Administrative Procedure Act (5 U.S.C. § 553(e))



The Next TSCA 30/30:
Wednesday, November 8th

For more information on past and future **TSCA 30/30** programs, please visit www.khlaw.com/tsca3030 and www.TSCAReformCenter.com for the most up-to-date TSCA news



THANK YOU



Sarvadi@khlaw.com
202.434.4249



Timmel@khlaw.com
202.434.4164