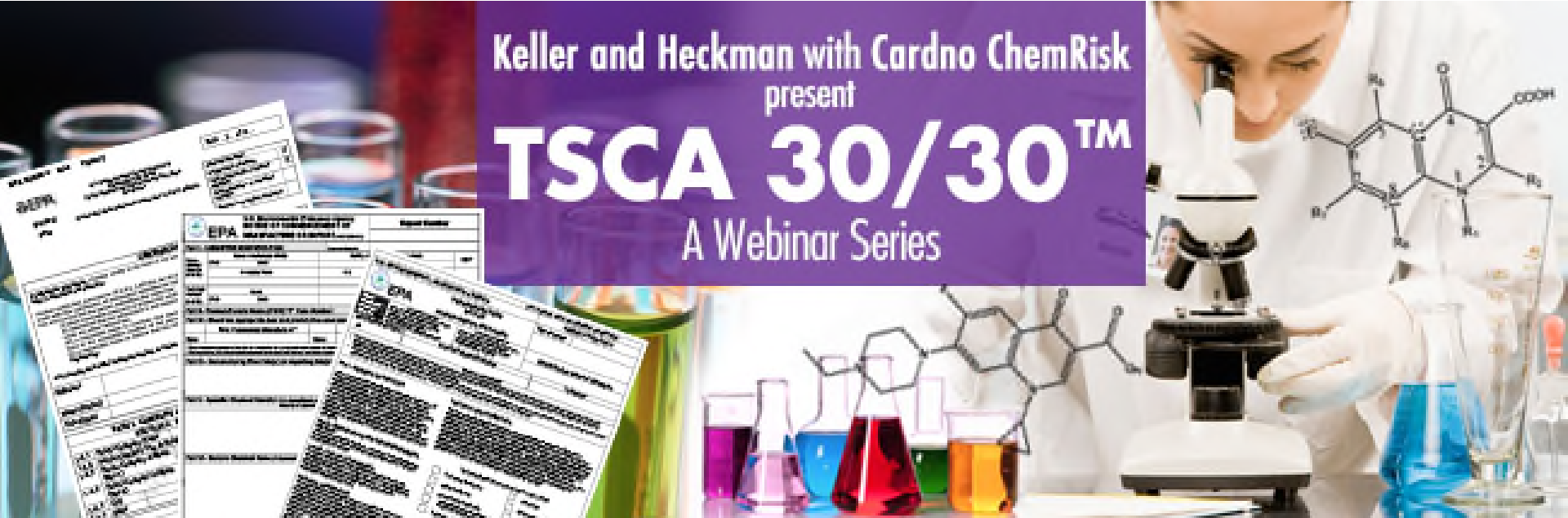


Keller and Heckman with Cardno ChemRisk
present

TSCA 30/30™

A Webinar Series



Claiming CBI and Substantiation Issues

November 9, 2016

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

 **Cardno
ChemRisk**
Shaping the Future



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)

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

 **Cardno**
ChemRisk
Shaping the Future

Adrienne 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

Heather Avens, PhD



Dr. Heather Avens is a chemical engineer and Supervising Health Scientist with Cardno ChemRisk. She has expertise in material science, polymer chemistry and engineered nanomaterials. She has performed research in industrial, academic, and consulting settings. Dr. Avens has applied her skill in exposure modeling to address a variety of issues including characterization of airborne particle settling rates, assessment of human health risk following landfill disposal, and airborne concentrations of volatiles emitted from chemical spills. She has provided litigation support in cases involving alleged exposures to asbestos-containing materials, benzene-containing products, hydrogen sulfide, sulfur dioxide, and PAHs.



heather.avens@cardno.com • 720.305.5832

Today's Agenda



- New CBI substantiation requirements and process
- Impact of reverse engineering, commercial and industrial intelligence
- EPA's recent implementation actions
- What companies should do

New Requirements to Protect CBI under Section 14



Basic Process:

1. Make CBI Claim
& Certification Concurrent with Underlying Filing
2. Substantiate & Recertify
 - In accordance with rules EPA “has” or “may” promulgate (40 CFR Parts 2, 700-799)
 - § 14(c)(2) exceptions
3. EPA 90-day review:
 - **100%** of all chemical identity CBI claims
 - At least **25%** of all other CBI claims
4. 10-year protection (opportunity for unlimited extensions)

NEW Certification Requirement



- Authorized official must certify that:
 - ✓ Company has taken **reasonable measures** to protect CBI;
 - ✓ I have determined the information is **not required to be disclosed** to the public under any other Federal law;
 - ✓ I have a reasonable basis to conclude that disclosure is likely to cause **substantial competitive harm**; and
 - ✓ I have a reasonable basis to believe that the information is **not readily discoverable through reverse engineering**.

§§ 14(c)(1)(B) & 14(c)(5)

- Knowing and willful misrepresentation subject to criminal penalty (18 U.S.C. § 1001). **No frivolous claims!!**
- Authorized official may need input from legal, business and technical teams to verify certification statement

Reverse Engineering Chemical Identity



Initial
Analysis

Phase
Separation

Chemical
Separations

Analytical
Testing and
Quantification

More difficult to reverse engineer:

Multi-phase substances

Chemical mixtures

Low quantity constituents

Chemical structures very distinct from existing libraries

- Issues for each process will be unique
 - Must consider what is already public or may be readily guessed
 - Will help inform how someone could “connect the dots”
 - How similar is the process to existing processes?
 - What unique details are key to protect?



- Waste streams
 - Relative release rate of constituents could reveal parent chemical
 - Absolute amounts released could reveal production rate
- Emission/Waste Controls
 - High efficiency of control technology could reveal the presence of novel control methods
 - Wastewater destined for POTW could indicate novel wastewater cleaning method on site

Less Intuitive Examples

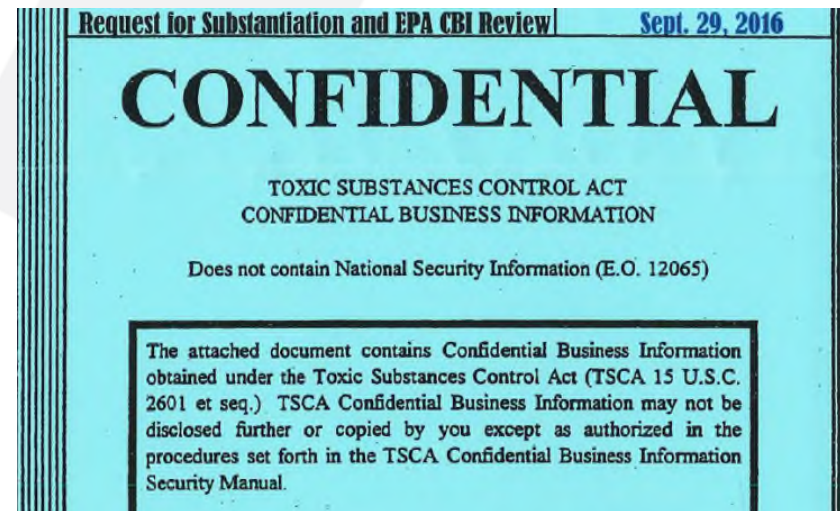


- Protective Equipment
 - Could hint at chemical identity of reactants or byproducts
 - Could hint at process rates or reaction rates
- Site Location
 - Public regulatory docs may already identify certain equipment or chemicals at the site
- Technical Contact Person
 - Is their name associated with this chemistry or process via other routes?
 - Regulatory docs, patents, publications, presentations, CV

EPA's Implementation So Far



- Issuing substantiation requests for:
 - Section 5 Notices - including PMNs, LVEs and *bona fide* requests
 - 2016 Chemical Data Reports
 - 12(b) Export Notifications
- Must respond in **15 working days from receipt!**
 - Extension requests sent to Office of General Counsel and “**unlikely to be approved**”
- EPA letter states CBI decision is “final”
 - Could potentially impact FOIA requests at a later date



Must Answer Numerous EPA Questions



RECEIVED
OPPT CBIC
2016 NOV -4 PM 1:11

Date and Time Stamp

COURIER RECEIPT

Company Name: Keller & Heckman

Received by: Beth

No. of Documents: 1 env


Environmental Protection Agency
TSCA Confidential Business Information Center
1200 Pennsylvania Avenue Washington, DC 20460

- **11 questions; 15 for CBI within health and safety filings**
 - Answer full set of questions per item or class of information
 - Reference page, paragraph and sentence where CBI appears
 - Insert bracketing around CBI in underlying filing and in substantiation response itself

What Can/Should You Do?



- Determine the already public aspects of your process
- Think outside the box to ensure key CBI is not revealed by non-obvious routes
- Claim only that information which can be substantiated as confidential and provide detailed responses to support claims
 - Responses should be unique – company, chemical, process and/or use specific
- Don't wait until day 15! Implement systems to address EPA substantiation requests early in the process:
 - Mail room should document when EPA request is received and forward it to appropriate person immediately
 - Ask questions early on . . . contact legal, technical and business teams as appropriate



Keller and Heckman with Cardno ChemRisk
present

TSCA 30/30™

A Webinar Series

The Next TSCA 30/30:
Wednesday, December 14th

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



Save the Date!

TSCA Implementation and Reform Seminar

Houston, TX

January 2017

For those of you interested in Workplace Safety and Health matters, check out our **OSHA 30/30** program. The next webinar is being held Wednesday, October 26th

Keller and Heckman with Cardno ChemRisk
present

TSCA 30/30™

A Webinar Series



THANK YOU



timmel@khlaw.com
202.434.4164



heather.avens@cardno.com
720.305.5832