What You Need to Know About TSCA Compliance in 2016

January 26, 2016
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Webinar Instructions

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The webinar will be recorded. The audio and visual presentation link will be sent to you after the webinar.
About 3E
The 3E Advantage

Value Proposition

Premiere EH&S Knowledgebase
- Broadest and largest
- Dynamic database of 3.7M SDSs
- Global regulatory database of 300,000 substances
- Only fully integrated provider of both product level SDS data and substance level regulatory data

24-7-365 Support
- Round the clock customer service / mission control
- Highly accessible, “on call” experts
- Global coverage and support

Accuracy & Quality
- Integrity of 3E’s data is a critical differentiator
- 99+% accuracy
- Data continuously updated from manufacturers

Full Lifecycle / Breadth of Solutions
- Span multiple verticals throughout the supply-chain
- Support many environments, including SAP EHS
- Support Upstream Manufacturer Product Stewardship and Downstream End-User Workplace Safety applications

Unparalleled Experience & Expertise
- Over 22 years of providing critical EH&S services to global customers
- Employees are domain experts with relevant degrees and certifications (i.e., environmental health, sciences, engineering; natural resources; chemical engineering; chemistry; law; hazardous materials management; toxicology)
While 3E Company makes every attempt to keep the information up to date and correct, we make no representations or warranties of any kind, express or implied. 3E Company expressly disclaims all liability in respect to actions taken or not taken based on any or all content of this webinar.
Ms. Julie Byrne is a Chemical Regulatory Consultant whose educational background is as a chemist. Ms. Byrne has experience in a laboratory environment and has 20 years experience in providing regulatory and EHS product stewardship guidance in the chemical industry.

Her focus is in supporting clients in the areas of worldwide chemical regulations (including US, Canada, China, Japan, Australia, Korea, and the EU) with a primary focus on US TSCA regulations.

Ms. Byrne is responsible for providing TSCA Compliance Services for clients, preparing compliance strategies including 2016 CDR reporting, preparing exemptions (such as Polymer and R&D) and submissions (PMN, LVE, NOC and SNUN) as part of 3E TSCA Services. Ms. Byrne also provides training and audit services via web and on-site as needed.
Barry F. McLaughlin
Authoring Project Manager/ TSCA Specialist

In his role at 3E Company, Barry F. McLaughlin serves as an SDS Authoring Project Manager and TSCA Compliance Services Specialist.

Mr. McLaughlin’s TSCA background includes assisting in the preparation of TSCA PMN and LVE notifications and auditing of overall TSCA Compliance programs. He has participated in 3E TSCA 2016 CDR training. He is also a certified PMP professional with expertise in various government compliance regulations, GMP and SOP documentation, and QC/QA procedures.
Agenda

- Update on TSCA
- 2015 Polymer Exemption Reporting
- Update on recent SNUR Activity
- 2016 TSCA Chemical Data Reporting (CDR)
- 3E Support for 2016 Chemical Data Reporting (CDR)
Update to TSCA Submissions

- As of January 19, you must submit TSCA notifications using web-based e-PMN software (*Thin Client*). EPA will no longer accept submissions through e-PMN software (*Thick Client*).

- Choose the user role under “CSPP: Submissions for Chemical Safety and Pesticides Programs” service; then choose “TSCA Section 5 Notices and Supports – e-PMN” (*Thin Client*) under "Chemical Information Submission System" (CISS)
Update to TSCA Submissions

• After January 19, you must use e-PMN software (Thin Client) through CDX to submit
  – Bona Fide Intent requests
  – to notify EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA
Toxic Substances Control Act (TSCA) Reform
Status of TSCA Reform Bill

- Approved in Senate on 12/17/15
- Senate and House now need to reconcile the versions into a joint committee bill
- Once the joint committee bill is finalized, the President must sign to make the bill into law
- Provides EPA more authority to ban chemicals and require testing
- Requires EPA to establish a risk-based approach to chemical assessment
- Requires EPA to review all chemicals currently in commerce to refresh TSCA inventory
Major Items in Reform Bill

• Will create a list of high priority chemicals to undergo full Safety Assessment, Safety Determination, and review against Safety Standards

• Will determine list of active chemicals in commerce and require notification to use previously determined inactive chemicals. “Re-set TSCA”

• New fee-based reviews
Major Items in Reform Bill – cont.

• Promote non-animal testing

• Review confidential TSCA inventory for CBI claims and requiring re-substantiation

• Promote industry consortia for joint testing and sharing of costs
<table>
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<th>Issue</th>
<th>Timeline</th>
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<tbody>
<tr>
<td>Develop Fees</td>
<td>1 year</td>
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<td>Prepare Sustainability Strategy</td>
<td>2 years</td>
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<tr>
<td>Implement Sustainability Strategy</td>
<td>3 years</td>
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<td>Plan for CBI allowances</td>
<td>5 years</td>
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<tr>
<td>Publish High Priority Chemical List</td>
<td>180 days</td>
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<td>Develop and implement policies for Section 4, 4A, 5, &amp; 6</td>
<td>2 years</td>
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<td>Develop guidance on Safety Assessments</td>
<td>1 year</td>
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<td>Develop strategic plan for alternative testing protocols</td>
<td>2 year</td>
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<td>Put together Science Safety Advisory Committee</td>
<td>1 year</td>
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<tr>
<td>Safety Determination Rule Promulgation</td>
<td>2 years</td>
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<tr>
<td>Plan for review of active/inactive chemicals</td>
<td>1 year</td>
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</table>
Recent SNUR Activity
Recent SNUR Activity

Withdrawn

• 3 SNURs withdrawn effective 12/1/15 for PMNs
  P-15-221  Isocyanate prepolymer (generic)
  P-15-247  Methylene diisocyanate polymer with diols and triols (generic)
  P-15-278  Polymer of isophorone diisocyanate and amine-terminated propoxylated polyol (generic)

because the Agency received notices of intent to submit adverse comments.
Recent SNUR Activity

SNURS issued for water releases

- 29 SNURs effective 2/2/16 issued to limit releases to water with limits for 24 under 5 ppb.
- 17 SNURs effective 12/1/15 issued to limit releases to water with limits for 15 under 50 ppb.

It is always a good idea to check... to see if your compliance efforts are affected by the recent SNURS.
2015 Polymer Exemption Reporting
Polymers in the US that meet the requirements in *40 CFR §723.250* do not require a chemical notification to be submitted prior to commercialization.

**But** you must provide written certification to the EPA by **January 31, 2016** (postmarked) of the number of any new polymers commercialized in the previous year—Electronic submission of the certification is not currently accepted.

Make sure that you send your certification letter by this **Saturday, January 30, 2016**.
2016 TSCA Chemical Data Reporting (CDR)
## 2016 TSCA Chemical Data Reporting (CDR)

**June 2016**

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<td>19 Fathers Day</td>
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CDR Summary

• Gives EPA a “snap shot” of chemicals in commerce including site of use, type of use and product use

• TSCA 8b listed substances are required to be reported if they exceed the threshold volumes

• Must report every four (4) years based on chemical volumes for each site not for each company

• 2016 report is for data from 2012 through 2015

• Reporting period starts Jun. 1, 2016 and ends Sep. 30, 2016

• There are a number of exemptions from reporting in 2016
2012 CDR

- In 2012, 1626 companies submitted 7674 chemicals and 4785 Form Us.

- 2012 data used in part to create “2014 TSCA Work Plan for Chemical Assessment”

- Work plan currently has 90 chemicals

- Will be used as basis for High Priority review under TSCA Reform
Exemptions Partial and Total

- **Partially Exempt** (exempt from processing and use reporting) chemical substances - “Petroleum Process Streams” (40 CFR §711.6(b))

- ** Totally exempt** substances - polymers (with certain exceptions), enzymes, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane (40 CFR § 711.6(a))

- **Totally exempt** - Microorganisms and naturally occurring chemical substances (40 CFR §710.4(b))
The following chemicals do not require reporting:

- **Full Exemptions:**
  1. CASRN 7732–18–5 Water
  2. CASRN 8006–14–2, Natural gas
  3. CASRN 8006–61–9, Gasoline, natural
  4. CASRN 64741-48-6, Natural gas (petroleum), raw liq. mix
  5. CASRN 68410–63–9, Natural gas, dried
  6. CASRN 68425–31–0, Gasoline (natural gas), natural
  7. CASRN 68919–39–1, Natural gas condensates
Small Manufacturer Exemption*

Under 40 CFR 704.3, a *small manufacturer or importer* means a manufacturer or importer that meets either of the following standards:

(1) A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lb.), the manufacturer or importer shall not qualify as small for purposes of reporting on the production at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

* Must report CAS RN > 2,500 lb. which have certain TSCA actions
Who needs to report\(^1\)?

- All chemical manufacturers
- All chemical importers
- Processors/Users of chemicals
- Suppliers that have not released chemical identity \(^2\)
- Toll manufacturers that have not released processing information \(^2\)

\(^1\) Based on volume
\(^2\) As joint submitter
What to Report in 2016?

- Must report if TSCA 8b listed substance exceeds the threshold maximums:
  - import or manufacture $\geq 2,500$ lb ($1,134$ kg/yr) if your substance is subject to
    - TSCA Section 5 (a)(2) SNURS
    - TSCA Section 5 (b)(4) Concern List
    - Section 6 Actions
    - An order under 5(e) or 5(f)
    - Or relief under a civil action through Sections 5 or 7
  - import or manufacture $\geq 25,000$ lb/year ($11,340$ kg/yr)

- 2012 volumes were 100,000 lb ($45,359$ kg/yr)

• Must report on volume for substance in **EACH** year since 2012 if threshold limit exceeded in **any** year

• Must report volumes for **each legal site**, not company

• Volumes only need to be reported if chemical is for commercial purposes. (R&D chemicals can be excluded.)

• There are exemptions that do not require reporting at any level

- For each reportable chemical at a legal site:
  - Chemical identification information
    - CASRN and Name
    - EPA Accession Number/generic chemical name (if on confidential TSCA inventory)
  - Annual volumes for 2012 – 2015
  - Type of activity (import/manufacture/processing)
  - Use
  - Number of workers likely to be exposed
  - Physical form and maximum concentration
Suggestions on where to start

• Make sure your company is prepared to submit

• Develop a plan to collect all chemical data for your site
  – Data collection can start anytime. The earlier the better to ensure timely submission

• Review 2012 report as a starting point

• Review any toll manufacturer agreements

• Don’t forget to include all chemicals at your site including intermediates, components of mixtures, and by-products
Suggestions on where to start - cont.

• Be certain what you have and don’t have. “Known to or reasonably ascertainable” (KRA) is used throughout e-PMN software.

  **Remember information can come from many sources in your company not just the EH&S department!**

• Combine import and manufactured volume for each chemical at your site

• Know the scope of the project
Suggestions on where to start - cont.

• Evaluate/consider whether your site will have any joint submissions (i.e. chemical composition(s) unknown to your site). Information may need to come from your supplier or toll manufacturer which can add time

• Evaluate your need to submit information confidentially

• Suggest compiling a master list of all chemicals at your site
Master List Preparation

• Once you have a master list of chemicals for your site, the reportable chemicals can be determined and any <2,500 lb. can be removed

  – Consider saving the complete master list as a listing of all chemicals at your site

• Identify those subject to lower reporting threshold of >2500 lb.

• Any chemical not subject to a SNUR or TSCA action and is <25,000 lb. can be removed from the CDR reporting list
Master List Preparation – cont.

• In addition to volume information, data for the “Principle Reporting Year” (2015) needs to be collected

  – Type of use or process

  – Concentration of chemical in use

  – # of workers and time of exposure

  – Industrial sector and function

  – Whether the chemical is for consumer or commercial use or whether it will be in a product intended for use by children
How do you submit your 2016 CDR?

• All submissions must be through e-PMN software and sent electronically to the EPA through CDX

• AO, SR, and Technical Contact need to be decided on and have an active CDX accounts and be linked to the site in e-PMN software and CDX

• Remember, CDX registration can be time consuming. If new accounts are needed, start early to ensure no problems

• AO is the **ONLY** person that can initiate, assign roles and submit a Form U
How do you submit your 2016 CDR?

• After June 1, 2016, AO needs to start the Form U in e-PMN software (*Thin Client*) for each site that they are responsible for and assign responsibility for SR and Technical Contact.

• AO will need to certify that the information is accurate and complete, claims of confidentiality are valid, and understand that there are civil and criminal penalties for not submitting and/or knowingly submitting incorrect information prior to submitting the report.
Adding Chemical Data to a Form U

• Data can be added one chemical at a time or uploaded from an .xml file.

• EPA will provide format of .xml early in 2016.

• Confidential Business Information (CBI) is allowed, but
  – Must be able to substantiate CBI
  – EPA must balance the needs of industry with the rights of the public to know what chemicals are in commerce
### PART III. PROCESSING AND USE INFORMATION

#### SECTION A. INDUSTRIAL PROCESSING AND USE

<table>
<thead>
<tr>
<th>a. Type of Process or Use</th>
<th>b. Sector(s)</th>
<th>c. Industrial Function Category</th>
<th>d. Percent Production Volume</th>
<th>e. Number of Sites</th>
<th>f. Number of Workers</th>
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#### SECTION B. CONSUMER AND COMMERCIAL USE

<table>
<thead>
<tr>
<th>a. Product Category</th>
<th>b. Consumer or Commercial Use</th>
<th>c. Used in Products Intended for</th>
<th>d. Percent Production Volume</th>
<th>e. Maximum Concentration</th>
<th>f. Number of Commercial Workers Reasonably Likely to be Exposed</th>
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</table>

*Substitution required for CBI claims on chemical identity, use identity, and processing or use information.

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**Paperwork Reduction Act Notice**

The annual public burden for this collection of information, which is approved under OMB Control Number 2010-0162, is estimated to be approximately 537 hours per response for a full report and 55 hours per response for a partial report. A full report includes manufacturing, processing, and use information. A partial report includes manufacturing information and does not include processing and use information. According to the Paperwork Reduction Act, "burden" means the time, effort, or financial resources expended by persons to generate, maintain, or disclose information to or for a Federal agency. For this collection it includes the time needed to review instructions, develop, acquire, update, and maintain information, and utilize technology and systems for the purposes of collecting, validating, and verifying information; providing training and managing information and, for collection instruments, developing, testing, and maintaining information collection instruments, including the cost to the agency to acquire any technology necessary for the information collection. The total annual burden is estimated to include 619 responses, with an average burden of 2.6 hours each. The estimated burden is 1,607 hours per year.

Send comments on the Agency’s need for this information, the accuracy of the provided burden estimate, and any suggested methods for minimizing respondent burden (including the use of automated collection techniques) to: Director, Collection Strategies Division, USEPA, Environmental Protection Agency (Mail Code 2226), 1200 Pennsylvania Ave, N.W., Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the completed form to this address. The request to submit information should be submitted in accordance with the instructions accompanying the form, or as specified in the instructions.
As you begin inputting data

• Once the Form U is created by the AO and roles assigned, data input does not need to occur in one session. Just make sure you save any information before exiting e-PMN software session.

• It is uncertain whether the e-PMN software will be available for Form U creation prior to June 1. The EPA has been asked to open e-PMN software for data input prior to June 1.

• Don’t have AO hit “submit button” until you are sure you are done entering data. It will save you from amending the data.
  – Data can be amended but the process is separate and distinct.
  – Data amendments must be completed by September 30.
A Joint Submission is required:

• If you have a chemical for which you do not know the identity
  
  – You must ask the supplier to provide the correct chemical identity information directly to EPA in a joint submission.
  
  – Request must include instructions for submitting chemical identity information electronically, using e-PMN software and CDX (see 40 CFR §711.35), and for clearly referencing the importer's submission.
Joint Submission – cont.

• If you have a toll manufacturer to whom you have not released the identity of a chemical to or you do not know the processing information
  – You must ask the toll manufacturer to submit directly to EPA any required information you do not have in a joint submission or to you as the submitter

• Supplier contact information, a trade name or other designation for the chemical substance and a copy of the request to the supplier must be included with the importer's submission with respect to the chemical substance
Joint Submission – cont.

• Your supplier or toll manufacturer will need to register in e-PMN software and CDX

• “Joint Submission” box in the Form U must be checked

• Name that toll manufacturer or supplier knows the chemical as must be used in your Form U

• Name of toll manufacturer or supplier must be included
Submission of Form U

• e-PMN software will validate that there is information where it is required to be

• Once the validation step is complete, file can be saved
  – You should also save before exiting each session

• When AO is ready to submit and the submit button is clicked
  – The data is encrypted
  – The form U is sent via CDX to the EPA
  – The CDR file is locked upon submission
  – The AO will have the option of saving a copy of the file after the submit button is pushed

• Amendments can be made to the Form U after submission but only as additional information
## CDR Form U from Industry Beta Testing

### SECTION 2.B - MANUFACTURING INFORMATION

#### Company Identification (2.B.1)
- Number of Workers (2.B.10)
- Max Concentration (2.B.11)
- Is chemical being recycled, remanufactured, reprocessed, reused, or reworked? (2.B.12)

#### Report CY 2015 Production Volume

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<th>Activity</th>
<th>Manufacture</th>
<th>Import</th>
<th>Volume Used on Site (2.B.8)</th>
<th>Volume Exported (2.B.9)</th>
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<tr>
<td>2.B.4</td>
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<tr>
<td>Domestically Manufactured (2.B.5)</td>
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<td>Imported (2.B.6)</td>
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<td>Imported Chemical Physically at Site (2.B.7)</td>
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<td>Total</td>
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#### Report Physical Form for 2015 Production Volume

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<th>% Production Volume of 12,800 lbs.</th>
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#### Report Past Production Volume (2.B.20)

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<td>Calendar Year 2012</td>
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Joint Submission Information

This information must be filled in if another company is going to provide confidential data.
Scenario #1 Volume Reporting

Chemical is not subject to TSCA Action

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<tr>
<td>2012</td>
<td>1,000 lb.</td>
</tr>
<tr>
<td>2013</td>
<td>10,000 lb.</td>
</tr>
<tr>
<td>2014</td>
<td>20,000 lb.</td>
</tr>
<tr>
<td>2015</td>
<td>25,500 lb.</td>
</tr>
</tbody>
</table>

Must report volumes for 2012, 2013, 2014, and 2015 (2015 principle year data must also include processing and use information)
### Chemical is subject to SNUR Issued in 2014

<table>
<thead>
<tr>
<th>Year</th>
<th>Volume (lb.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>1,000</td>
</tr>
<tr>
<td>2013</td>
<td>1,500</td>
</tr>
<tr>
<td>2014</td>
<td>1,750</td>
</tr>
<tr>
<td>2015</td>
<td>2,250</td>
</tr>
</tbody>
</table>


Do not have to report even though subject to a SNUR.
### Scenario #3  Exemption

**Company is a Rubber Manufacturer**

<table>
<thead>
<tr>
<th>Year</th>
<th>PV</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>10,000 lb.</td>
</tr>
<tr>
<td>2013</td>
<td>26,000 lb.</td>
</tr>
<tr>
<td>2014</td>
<td>5,000 lb.</td>
</tr>
<tr>
<td>2015</td>
<td>3,250 lb.</td>
</tr>
</tbody>
</table>

Rubber is a totally exempt chemical substance. **Do not have to report.**
Recordkeeping

• Make sure that you have plans to save your documentation.
  – Records must be kept for five (5) years
  – 2012 data must be kept until June 30, 2017
  – 2016 data must be kept until September 30, 2021
  – May want to keep for longer as reference documents for future reporting
• The 2016 CDR is like any other TSCA regulation when it comes to enforcement
  – It is illegal not to submit the 2016 CDR, not keep required records and not allow an EPA audit

• EPA can impose civil and criminal penalties
  – Up to $37,500 for each violation (civil, criminal)

• EPA did impose fines for violations of failure to report under the 2006 IUR (Inventory Update Rule)

• Not knowing about the regulation is not accepted as a reason for failing to report
Important items to remember

• In determining whether a chemical is subject to a TSCA action, June 1, 2016 is the important date to remember
  – If a TSCA action sunsets before June 1, 2016, lower threshold requirements are not considered for all reporting years (2012-2015)
  – If a TSCA action is in effect on June 1, 2016, you must consider it for all reporting years (2012-2015)
Important items to remember – cont.

- If a chemical is subject to multiple TSCA actions, make sure to review carefully. Deciding on whether a small manufacturer exemption can be used or whether a lower reporting threshold is required can be tricky.

- June 1 is fast approaching! Make sure your company has a plan and is prepared for the reporting requirement.

- With TSCA Reform on the horizon, your initial master list of all chemicals, independent of volume, can be a starting point in identifying chemicals in commerce for your company.
Guidance Documents - Resources

EPA Website CDR
http://www.epa.gov/chemical-data-reporting
Contains information on CDR, e-CDRweb, exemptions, CDX, timelines, etc.

CDR Help Desk  ecdrweb@epa.gov

CDX Help Desk  1-888-890-1995  helpdesk@epacdx.net

CBI webpage  http://www.epa.gov/tsca-cbi
How can 3E Company help?

• 3E is prepared to offer multiple levels of consulting services to help your company successfully meet your 2016 CDR obligation.
  – Help with CDR planning
  – Help with preparing master list
  – Determination of reportable chemicals
  – Completion of Form U
Poll Question #1

Are you interested in speaking with a 3E specialist regarding assistance in TSCA/CDR compliance?
Upcoming Webinars

• **GHS Compliance and 3E Online**
  January 28 at 8am PST

• **California Prop 65 – What you Need to Know**
  February 4 at 8am PST

• **How 3E Can Help You Prepare For Your Next Chemical Spill or Release**
  February 9 at 10am PST
Upcoming Events

• Modern Supply Chain Experience
  Jan 25-27 (San Jose, CA)

• Chemical Watch Biocides USA
  Jan 26-27 (San Jose, CA)

To learn more about upcoming events or to register—please go to 3ecompany.com
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Thank you!