Exploring the EPA’s Chemical Data Reporting (CDR) Rule

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September 10, 2012
Introductions

Kami Blake – Speaker

- Assess regulatory requirements, information management technology and effectiveness of existing HazMat programs to develop and re-engineer compliance solutions
- Prior to joining 3E in 2002, served in Quality Assurance, Supply Chain Management and Process Engineering roles in the biotech and medical device manufacturing industries
- U.S. Marine
  - Computer Programmer / Systems Analyst
  - Two time Navy Achievement Medal recipient for small systems implementation and training
Agenda

- TSCA Reform Overview
- Challenges with CDR Reporting
- Compliance Strategies
- Preparation for Future Reporting
  - Preparation for Future Reporting
  - Corrections to 2012 Submissions
  - Lessons Learned
- Learning Objectives: Practical App of TSCA Reform
Important Toxic Substances Control Act (TSCA) Sections

Section 3 – Definitions

Section 4 – Test rules/orders

Section 5 – Pre Manufacture Notification

Section 6 – Unreasonable Risk Regulation

Section 8 – Recordkeeping and Reporting

Section 12 – Exports

Section 13 – Imports

Sections 15 and 16 – Penalties
Previously, the Inventory Update Reporting (IUR) rule required manufacturers (including importers) of certain chemical substances on the TSCA Chemical Substance Inventory (TSCA Inventory) to report information regarding the …

• Manufacturing (including import)
• Processing
• Use

... of those chemical substances.
TSCA Inventory currently has about 84,000 chemicals.
IUR to CDR Timeline

- August 2010, the EPA proposed amendments to the IUR rule
- May 11, 2011 EPA suspended 2011 IUR Submission Period
- August 2, 2011, EPA released a pre-publication final Amended IUR rule named the Chemical Data Reporting (CDR) rule
- August 16, 2011, the EPA formally updated the IUR and published the CDR rule in the Federal Register
  → 40 CFR 710.23-710.39 and 710.43-710.59 removed and new 40 CFR Part 711 TSCA CDR added
- September 6, 2011, final revision published to the CDR rule
- On June 11, 2012, the original deadline of June 30 extended to **Aug. 13th, 2012**.
Other Key Changes

- Reporting volume of ≥ 25,000 lbs. in any calendar year
- Reductions in Processing and Use Threshold
- Mandatory electronic reporting (e-CDRweb) via Internet
- CDR enables the EPA to collect and publish data on manufacturing sites and the manufacturing, processing, and use of chemical substances
- Upfront substantiation for CBI
- 4 Year Reporting Cycle
- Elaboration on “Byproducts”
- New exemptions
  - Electronic reporting requirement
  - Reporting frequency decreased from 5 years to 4 years
  - Increased transparency and public access to information
  - Subjective “readily obtainable” reporting standard replaced with objective “known to” or “reasonably ascertainable by” standard
Who Does/Doesn’t Report?

Manufacturers and Importers DO

• To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage
• Applies to chemical produced coincidentally during manufacture, processing, use, or disposal of another substance/mixture, including byproducts that are separated and impurities that remain in a substance/mixture

Processors DON’T

• The preparation of a chemical substance or mixture AFTER its manufacture for DISTRIBUTION IN COMMERCE with the purpose of obtaining an immediate or eventual commercial advantage for the processor.

*Do not get confused with the requirement on reporting “processing” information. The word, processing, is mentioned quite often but CDR does not apply to processors.
Who Reports?

Per EPA guidelines, there are two kinds of submitters:

1. **Authorized Official (AO)**
   Person legally responsible for the site’s CDR submission, who can certify the form – typically a senior staff member with management responsibility for the person (or persons) completing the form.

2. **Support Registrant (SR)**
   Person designated by the AO to provide supporting information for submission (i.e. on-site contact, a technical contact, employee, or an agent) – may enter and modify data SRs but not permitted to certify the CDR submission.
Who Reports?

For manufacturers in the U.S., it seems simple. For importers, it can be more complicated

If your company is an importer, headquartered internationally, using a U.S. agent to receive chemicals then

– Who certifies the Form-U and who fills it out?
– The Company official outside the U.S., or the agent in the U.S.?
Who Reports?

- Under 40 CFR 704.3 “Importer means any person who imports any chemical substance... into the customs territory of the U.S., and includes... (ii) an authorized agent acting on his/her behalf...”

- Therefore, the agent in the U.S. acts as an AO for a U.S. site

- However, the international party can act as a SR if they are more knowledgeable about the chemical substances being imported

- This Support Registrant can fill out the form but cannot certify it
Who Reports?

In cases where the international company is a supplier to a manufacturer or importer in the U.S., and they want to keep the chemical identity confidential,

- The U.S. manufacturer can begin a Form U and create a joint submission.
- The international supplier can send in the chemical identity directly to EPA.
- U.S. manufacturer = the Primary AO (and can be Primary SR)
- International supplier = the Secondary AO (Secondary SR)
- Third party AOs and SRs can exist and may be necessary depending on the number of confidential substances from different suppliers.
### Exclusions & Exemptions

<table>
<thead>
<tr>
<th>Exemption</th>
<th>Criteria</th>
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<tbody>
<tr>
<td>Manufacture/Import for R&amp;D only Exemption</td>
<td>Small quantities (reasonably necessary)</td>
</tr>
<tr>
<td>Small Manufacturer/Importer Exemption</td>
<td>&lt;$4 million/year in total sales</td>
</tr>
<tr>
<td>Small Manufacturer/Importer Exemption</td>
<td>&lt;$40 million/year AND &lt;100,000 lbs. in the production volume at any site</td>
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</tbody>
</table>
What to Report?

For the 2012 CDR

1. **Site Identification Information**
2. **Manufacturing Information**
   - Production volume of 25,000 lb or more during the principal reporting year (PRY of year 2011)
   - Production volume during 2010
   - Non-CBI chemicals = CAS RN and CA index name
   - CBI chemicals = accession # and generic chemical name
   - # of workers reasonably likely to be exposed in ranges
   - Max concentration, physical form, and % PV in the form
   - Whether a substance is being recycled, remanufactured, reprocessed or reused (issue of “byproduct”)
What to Report?

3. Processing and Use Information

- For each reportable substance with a 2011 production volume of **100,000 lbs** or more
- Changed from 300,000 lbs in IUR
- More information to report if PV is high
- Industrial Processing and Use (up to 10 combinations to select)
- Commercial and Consumer Use (up to 10 product categories)
What to Report: Exemptions

- 40 CFR 711.6(b), Partially Exempt (exempt from processing and use reporting) Chemical Substances Termed “Petroleum Process Streams” For Purposes of Inventory Update Reporting and Partially Exempt Chemical Substances are listed

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

- Microorganisms and naturally occurring chemical substances as described in 40 CFR 710.4(b) are also exempt
What to Report: Exemptions

Additionally, under the new CDR rule, the following will be fully exempt:

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
New Rules for CBI: Focus on Transparency

- Provide upfront substantiation for each processing and use data element claimed as CBI. Submitters cannot claim those data elements as confidential when they are identified as “not known to or reasonably ascertainable by”. Rejection of confidentially claims have significantly increased.

- **What does that mean?**
  - Higher standard for claiming CBI
  - Identity and use data of the substance must be reported
  - Generic chemical name must be provided
  - Increased public access to previously restricted information
## Impact of Definitions under CFR

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readily obtainable</td>
<td>710.43 - Information which is known by management and supervisory employees of the submitter company who are responsible for manufacturing... Extensive file searches are not required.</td>
</tr>
<tr>
<td>Known to or reasonably ascertainable by</td>
<td>704.3 - All information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.</td>
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</tbody>
</table>
Byproducts are NOT subject to reporting if they are not used for a commercial purpose.

- Under 720.30(g) or (h) byproduct is excluded from reporting, if a manufacturer (1) burns it as a fuel, (2) disposes of it as a waste, or (3) extract component chemical substances from it for commercial purposes.

EPA provides a complex set of instructions and scenarios
Byproducts

Affected Industries

• Chemical manufacturers and importers
• Chemical byproduct users and processors
• Electronic component manufacturers
• Utilities
• Paper manufactures
• Metal Manufacturers
Definitions:

“40 CFR 704.3 - A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.”

This also includes

• **Mixture** – any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or part, the result of a chemical reaction...(TSCA Section 3). *Not included in the TSCA Inventory.*

• **Complex Byproduct** – can be identified as UVCB substances that represent the process stream. Volumes of individual substances do not need to be determined. *Included in the TSCA Inventory.*

• **Impurity** – a chemical substance which is unintentionally present with another chemical substance.
Challenges: Byproducts

When is a Byproduct Subject to the CDR Rule?

- TSCA Inventory
  - Byproduct is listed on the TSCA Inventory.

- Commercial Purpose
  - Byproduct is used for a non-exempt commercial purpose.

- Production Volume Threshold
  - Byproduct is manufactured in volumes of 25,000 pounds or more during the principal reporting year at a single site.
A byproduct is EXEMPT if: (1) it is not used for a commercial purpose, or (2) “its only commercial purpose is for use by public or private organizations that:

a) burn it as fuel,
b) dispose of it as waste, including in a landfill or for enriching soil, or
c) extract component chemical substances from it for commercial purposes.”* 40 CFR 720.30 (g) and (h)(2)

*Note that this last part of the exemption only applies to the byproduct, and not to the extracted component chemical substance.
How does the company determine chemical identification of a byproduct to comply with the reporting element “Is Chemical Substance Being Recycled, Remanufactured, or Reused”?

Generally, EPA considers each combination of substances resulting from a reaction to be either:

1. A mixture, composed of two or more well-defined chemical substances (named and listed separately) or
2. A reaction product, to be listed as a single chemical substance, using one name that collectively describes the products, or, the reactants used to make the products
Byproducts

Gray Areas – excerpts from EPA 16-page Guidance Document
(http://www.epa.gov/iur/tools/Q&A_DOCUMENT-Recycling_and_TSCA_Chemical_Substance_Inventory%20-revised%208-11.pdf)

• Is it possible I am manufacturing a chemical byproduct in the course of manufacturing an article?
  Response: Yes, potentially.

• Is a byproduct required to be listed on or added to the TSCA Chemical Substance Inventory (the Inventory)? Are byproducts not listed on the TSCA Inventory subject to the TSCA section 5 PMN requirements?
  Response: It depends.

• Are some byproducts with a commercial purpose exempted from the TSCA Inventory listing requirement?
  Response: In some circumstances.
Postponement Request

On January 13, 2012, Chairman of the Committee on Energy and Commerce, Congressman Fred Upton, sent a letter to EPA administrator, Lisa Jackson, requesting to postpone the implementation deadlines of the CDR regulation.

Unofficial EPA Response

3E was advised this past Monday by an important, high-level EPA source that no delay is planned. It was stated that this would be unfair to those who, through substantial effort and expense, are prepared to comply with the standard. It was mentioned that there is a possibility of extending but NOT postponing the deadline. Our source was clear that the EPA is still pursuing compliance, as scheduled, with the CDR regulation.
Byproduct reporting

- [http://www.epa.gov/iur/tools/training/Training_Module_7.pdf](http://www.epa.gov/iur/tools/training/Training_Module_7.pdf)
Difficulties with 2012 Submission

Technical Difficulties with eCDRweb

1. System glitches- slowness, system freeze, error messages, temporarily out of service, etc.
2. Document your form U information separately.
3. One more month to file.
Heightened disclosure level for Processing and Use Information

- For each reportable substance with a 2011 production volume of **100,000 lbs** or more
- Changed from 300,000 lbs in IUR
- More information to report if PV is high.
- Industrial Processing and Use (up to 10 combinations to select)
- Commercial and Consumer Use (up to 10 product categories)
Difficulties with 2012 Submission

- Complicated codes to select
- For Consumer and Commercial Use Data, designate up to 10 product categories which correspond to the actual use of the chemical substance
- 33 product categories are under the main topics of:
  1) Chemical Substances in Furnishing, Cleaning, Treatment/Care Products
  2) Construction, Paint, Electrical, and Metal Products
  3) Packaging, Paper, Plastic, Hobby Products
  4) Automotive, Fuel, Agriculture, Outdoor Use Products
  5) Chemical Substances in Products not Described by Other Codes

Difficulties with 2012 Submission

• Provide upfront substantiation for each processing and use data element claimed as CBI. Submitters cannot claim those data elements as confidential when they are identified as “not known to or reasonably ascertainable by”.

• What does that mean?
  - Higher standard for claiming CBI
  - You must report the identity and use data of the substance.
  - Provide EPA the generic chemical name.
Difficulties with 2012 Submission

- Reporting standard changed for processing and use information
  - **Old:** “Readily obtainable” standard (subjective to the submitter)
  - **New:** “Known to or reasonably ascertainable” standard (objective to a reasonable person)
  - How to determine what is reasonable??
Difficulties with 2012 Submission

The Main Lesson

- Document, document, document
- Prepare all ascertainable information
- Keep detailed and comprehensive records
- Maintain all historical information indefinitely
- Justify all applicable exemptions
- Proactively submit corrections, as necessary
Compliance Strategies

Program/Process:

• Data Gathering – best practice, automated reports that can “drop” into Form U
  → taking a look at 2006 records may be instructive
  → don’t forget 2011 data that applies
• Data Review – confirm accuracy and applicability
• Data Input – complete Form U
• Submit – AO to push the button
• Save records
## Compliance Strategies

### People – Super 7 set of roles

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
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<tbody>
<tr>
<td>AO</td>
<td>Responsible official, signs and submits</td>
</tr>
<tr>
<td>SR</td>
<td>Can be Consultant, fills in Form U</td>
</tr>
<tr>
<td>IT</td>
<td>Install software, trouble shoot with EPA helpdesk, development programs for interface between your data reports and electronic Form U</td>
</tr>
<tr>
<td>TSCA Specialist</td>
<td>QA for compliance, confidentiality claims...can be SR</td>
</tr>
<tr>
<td>Site Production Manager</td>
<td>Confirm data for Part II and III</td>
</tr>
<tr>
<td>Sales and Marketing Managers</td>
<td>Confirm data for Part II and III, track new rules and revisions for P &amp; U data/reporting requirements</td>
</tr>
<tr>
<td>Supply Chain Manager</td>
<td>Confirm data for Parts I, II, and III</td>
</tr>
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Compliance Strategies

Preparation and Planning

1. Now! – we are out of time
2. Are flags set?
3. Are exemptions confirmed? (subscription based lists can assist)
4. Is Team trained, orientation complete, R&R clearly defined?
5. Are AO and SR CDX-registered?
6. Is e-CDRweb functional?
7. Do you have D&B numbers?
8. What data points will be claimed as confidential? Why?
9. Has Management committed – OT$ may be well spent!
Managed risk through organizational commitment

- Resources
- Budget

<table>
<thead>
<tr>
<th>Investment</th>
<th>Return</th>
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<tbody>
<tr>
<td>Data Management</td>
<td>Access, Aggregate, Integrate and Analyze multiple data sources (internal and external)</td>
</tr>
<tr>
<td>Expertise &amp; Proficiency</td>
<td>At all levels of participation, utilizing internal staff and third party SMEs</td>
</tr>
<tr>
<td>Environmental Systems</td>
<td>Integrated infrastructure to push/pull data, provide necessary decision making tools</td>
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Risk: $24,000 Per Chemical / Per Site
2016 Highlights

- Processing and use info. threshold further reduced to 25,000 lb/year from 100,000 lb. of the 2012 CDR
- Must report on substance if 25,000 lb threshold is exceeded in any calendar year since 2012
- Must report on PV for substance in each year since 2012
- For example:

<table>
<thead>
<tr>
<th>Year</th>
<th>PV (lb)</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>25,000</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

(2014 data must include processing and use information)
For the 2012 CDR, no chemical substance under the 25,000 lbs production volume needs to be reported.

However for the **2016 CDR**, if your substance is subject to:

- TSCA section 5(a)(2) SNURs;
- Section 5(b)(4) Concern List;
- Section 6 Actions;
- An order under 5(e) or 5(f);
- Or relief under a civil action through section 5 or 7;

Then you must report under the CDR if you import or manufacture equal or greater than 2,500 lbs.
Preparation for the Future

Possible EPA Inspections and Citations

• Strict Liability for Violations or Failure to Report
• Penalties up to $24,000/Chemical/Site
• Cooperate and provide documentation
1. What should a submitter do if and when he/she discovers an error in the 2012 CDR filing after Aug. 13th deadline and after the form U has been filed?

2. What are the possible repercussions for correcting an error?
Preparation for the Future

Answers:

1. Log onto CDX and access the original submitted Form U. Unlock the form and edit as needed before or after Aug. 13. An Authorized Official or a Support Registrant may make changes but only the Authorized Official can certify and submit the form.

2. The act of correcting errors in Form U submission does not absolve the submitter of possible enforcement action from any CDR rule violations.
Preparation for the Future

- **CDR Submission Corrections**
  - Make corrections but that does NOT grant immunity from punitive measures by the EPA. (Strict Liability)
  - Always better to self-correct
  - Historic pattern of IUR violations has been mostly egregious, deliberate and without regard to the necessity to comply.
  - EPA has recognized and acknowledged good faith efforts to comply and has helped to mitigate potential fines for non-compliance
Preparation for the Future

• Lessons

- Establish a contact with EPA
- Ask questions and seek help if needed….demonstrates good faith efforts to comply
- Document, document, document
- Enlist professional TSCA consulting services
- Industry association such as SOCMA can assist you with training and communicating with EPA
CDR Information Resources

  - Contains link to the Federal Register
  - Training and Workshops
  - Guidance Documents
  - Electronic Reporting User Guides and Schemas
- http://www.epa.gov/cdx/index.htm
  - Home page for Central Data Exchange
- TSCA-Hotline@epa.gov
- eCDRweb@epa.gov
- 3E Ariel database
- 3E Company’s CDR Services
Learning Objectives

1. To gain a high-level understanding of the applicable TSCA regulations
   a. Major directives and mandates
   b. Regulatory parameters for the TSCA Inventory, New and Existing chemicals and Enforcement
   c. Exclusions
   d. Responsible parties

2. Integrating TSCA Compliance into your organizational “Idea to Market”
Learning Objectives

3. Access and Search the TSCA Inventory
4. Identify and categorize the differences (definitions and compliance requirements) between “substances” and “mixtures”
5. Understand the requirements for New Substance Notifications
6. Identify and apply exemptions
7. Understand the e-TSCA Framework
8. Summary of TSCA application and scope
Learning Objectives 1:

To gain a high-level understanding of the applicable TSCA regulations

1. Scope Discussion
2. Compliance Challenges
3. Required Resources (internal and external)
4. Compliance Considerations
Learning Objective 1: Scope: Major Deals

- **Section 4**, authorizes EPA to require testing of certain chemical substances or mixtures to determine potential risk to human health or the environment; (any all links to 12b)

- **Section 5**, grants EPA authority to regulate the manufacture, processing, distribution in commerce, use, and disposal and to require testing of new chemical substances or significant new uses of existing chemical substances; (cradle to grave, PMNs et al)

- **Section 6**, provides EPA with authority to regulate the manufacture, processing, distribution in commerce, and use and disposal of chemical substances; (existing)

- **Section 8**, requires manufacturers and others to keep certain records and to submit reports to EPA; (a, b, c, d, e)

- **Section 12**, requires exporters to notify EPA when exporting certain chemicals (export)

- **Section 13**, requires importers to certify the TSCA status of the chemicals in an import shipment (import)
40 CFR Part 720
The Inventory - Section 8 (b) of the Toxic Substances Control Act (TSCA) requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States.

New Chemicals – Section § 5(a) (1) (B)
“...prohibits manufacture of any new chemical substance unless manufacturer submits a PMN...”

Existing Chemicals - Section § 6
gives EPA the authority to protect against unreasonable risk of injury to health or the environment from “existing” chemical substances.

Enforcement – Section §§ 11, 15, 16, 17 –
Gives EPA the authority to inspect establishments, lists prohibited acts and their penalties eg. “$32,500 per day, per violation; may include imprisonment”
Learning Objective 1: Scope: Exclusions

40 CFR § 720.30

The notification requirements of TSCA §5 APPLY only to chemical substances. It specifically excludes (UNLESS they are intended for a “TSCA Use”)

- Mixtures (their components must be listed)
- Pesticides [FIFRA]
- Tobacco and Tobacco products
- Radioactive Materials [Atomic Energy Act]
- Firearms and Shells
- Articles
- Foods, Food additives, Drug, Cosmetics, Device [FFD&CA]
- Exemptions (polymer, R&D, (h)(7), for export only)
Learning Objective 1: Scope: The Responsible Parties

- Required and administered by EPA
- Applies to all parties developing new, manufacturing/importing, processing, distributing and disposing regulated chemicals in the US
- Required from TSCA trained personnel to assure compliance
- Requires responsible signatures
Learning Objective 1: Summary of TSCA Regulations

• Compliance Challenges
  – Broad Scope
  – On-going Regulatory Reform (non-legislative, through agency interpretation)
  – Increased data requirements
  – No one-size fits all automated system

• Required Resources (internal and external)
  – Internal expertise at the substance, mixture and product-level
  – Technical and regulatory expertise and tracking
  – Automated infrastructure
  – 3rd Party expertise and solutions

• Compliance Considerations
  – # of sites, production volume
  – Alternate formulations
Learning Objectives 1:

Integrating TSCA Compliance into your organizational “Idea to Market”

1. Chemistry and Function
2. Practical Steps
3. Limitations and Constraints
Chemistry and Function:

1. Who will make it? Chem-Trend or other vendors
2. Where ill it be manufactured? U.S. or overseas
3. Who will use it? Industrial, professionally, consumers, children
4. For what purpose will substance be used? Function and end-use
5. Where will substance be used? Industry, state
6. Who regulates substance? EPA, TSCA, is status listed
7. How is substance regulated? Orders or rules or actions
8. What thresholds/restrictions/requirements apply for status?
Learning Objective 2: Practical Steps

1. Incorporate TSCA and global inventory review as part of R&D, Innovation, Development

2. Seek certification from all vendors for TSCA status/requirements [yes/no = best]

3. Develop standardized review process/formats/content/records (MSDSs by disclaimer may not serve you well)

4. Incorporate EPA SF modules into your review and submission processes
Learning Objective 2: Limitations and Constraints

- Determination on whether new chemistry, new use, new process
- Components need to be on Inventory - due diligence for fillers, stabilizers, etc.
- Having a CAS RN does NOT mean chemical substance is listed on Inventory
- No threshold below which components of a mixture may be ignored for Section 5
How to search the Inventory

1. **Public**
   1. Search
      
      www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html
   2. Utilize Ariel WI or STN or other reputable search
   3. Seek supplier certification (not merely on MSDS)

2. **Confidential**
   1. *Bonafide*
   2. Seek supplier certification (with accession #s)
Opportunities


- [www.epa.gov/oppt/existingchemicals/pubs/tscainventory/index.html](www.epa.gov/oppt/existingchemicals/pubs/tscainventory/index.html).
"Chemical substance" is defined in section 3 of TSCA (and in section 710 of the Agency's implementing regulations) by chemical composition, by source or origin and by identification of certain categories of materials that are not considered "chemical substances":

"Chemical substance" means any organic or inorganic substance of a particular molecular identity, including:

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, ...

"Chemical substance" does not include:

(i) any mixture [710.2(q)], ...
Mixtures =

"Mixture" is defined in section 710.2(q) as:

any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that "mixture" does include:

(1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date of premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.
New Substance Process

- Search existing
- Procure new or confirm existing CAS RN
- Gather as much data and information as available
- Seek exemption – LVE, R&D, Polymer, For export only
- File PMN
- Comply with EPA regulatory action
Chemicals of Concern

1. All: toxic, with –ve press, with adverse environmental impact, under enforcement
2. Perfluoroalkyl groups
3. Action Plans, Priority Listed
4. Polymers
5. PCBs
6. PBTs
Is the formula viable?

• Are all chemical components on the Inventory?
  – If No, file Section 5 or seek exemption
  – If Yes, ascertain requirements, proceed

• Is finished product on the Inventory?
  – Is it required to be (mixture or substance?)
  – If yes, file Section 5 or seek exemption
  – If no, is use regulated by TSCA?

• Are any regulated by Sections 4, 5, 6, 7, 8, or 12b?
  – If yes, comply - file required notifications, notify/advise downstream
Categories of Concern
Consent Orders
SNURs → SNUNs
No data or information
Without efforts to mitigate effects
<table>
<thead>
<tr>
<th>Sustainable Futures</th>
<th>EPI Suite</th>
<th>ECOSAR</th>
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<tbody>
<tr>
<td>PBT Profiler</td>
<td>Oncologic</td>
<td></td>
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<tr>
<td>Analog ID Methodology</td>
<td>Non Cancer</td>
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<td>ChemAce</td>
<td>E-FAST</td>
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Relief by exemptions

LVE

**PROs**

– Free
– Minimum 30 day vs 90 day EPA review
– Allows for exclusivity
– May not include data/information at sites not controlled

**CONs**

– Not listed on Inventory
– Up to 10,000kg per year
– All details are binding
– May still have to file (subsequent) PMN
For EPA Polymers only

- Must meet several criteria
  - Meet EPA definition
  - Specific MW distribution
    - Heavy metal
    - Water absorbing
- Self – executing
- Requires one notification by Jan 31 of following year
- Requires (internal) certification {several companies provide PEA assurance service}
R&D Exemption

• Must keep certain records
• Must notify downstream users
• Self-executing
• Under the supervision of trained personnel
• “Small Quantities” = sufficient for the SOLE purpose of research and development
• Not necessary for Prudent Lab Practices → all available information must be reviewed and evaluated for actual or potential risk during exposure
Things to note:

1. TSCA has wide authority and will use IT
2. TSCA protects human life and the environment
3. TSCA is dynamic law
4. TSCA covers all not otherwise excluded or exempted (eg. food, drugs, cosmetics, pesticides)
5. TSCA applies from cradle [idea] to grave [end of product life cycle]
e-TSCA

- PMNs
- CDR
- 8e
  - Requires AO and allows for SR
  - All done electronically – all to web-based
  - Allows for direct uploads thru xml
  - Is high on security and confidentiality
  - Often transmission quirks/glitches due to firewall issues
Only scratched the surface!

Thank You!