Chemical Management in the US

- General Introduction of TSCA
- Amended TSCA
- Amended TSCA & Current Status
- Others
Chemical Management in the US

**TSCA (Toxic Substances Control Act)**

*Enacted: October 11, 1976*

*Effective: January 1, 1977*

*Administered: United States Environmental Protection Agency (EPA)*

*In 40 years..., amended on June 22, 2016*

**United States Code (U.S. Code):** Title 15 - Commerce and Trade

Chapter 53 - Toxic Substances Control Act

**The Code of Federal Regulations (CFR):** Title 40 - Protection of Environment
TSCA - General Introduction

When you manufacture or import your chemical substance in the U.S. for commercial purposes,

TSCA Inventory

Public Part / Confidential Part (No. of the substance listed as of April, 2018: 85,000 --- from EPA site)

Listed: Existing substance
Can be used (still, refer to the identification)

Not listed: New substance
Needs to be notified

Type of Notification:
PMN / Pre-manufacture Notification
Exemption from PMN
- LVE / Low Volume Exemption
- Polymer Exemption etc.

Notification Documents
Data
※ No fixed data-set
※ CBI claim
※ Information supply from supplier

CDX (Central Data Exchange)
On-line submission
Only the manufacturer and importer as business entity in US can submit

EPA Review
After the completion of review, submitter notifies commencement of manufacture

5/24/2018 www.knoell.com
**PMN Flow**

1. Submission of PMN to EPA
2. Receipt and Quick review at EPA
3. Notice of commencing Evaluation from EPA
   - Evaluation Period: 90 days
   - Postpone (by EPA): maximum 90 days
   - Notice or inquires possible from EPA
     → may cause delays in evaluation
4. Notice of evaluation results from EPA

Amended TSCA

To make chemical management under TSCA more workable...

EPA is required to ...
- re-evaluate existing chemicals listed on the inventory
- promulgate a number of rules to set up the procedures EPA will use to implement, and otherwise align, EPA’s chemical management program with the new requirements and responsibilities in the law.

Strengthened EPA’s authority... (TSCA Sec. 4, 5 &6)
- Data and tests requirements...
- Regulations ...

**Framework Rules**
- Active/Inactive Inventory Notification Rule
- Prioritization Rule
- Risk Evaluation Rule
- Fee Rule

**Other requirements**
- Existing and New Chemicals
- CBI (Confidential Business Information)
- Mercury
Amended TSCA

Active / Inactive Inventory Reporting Rule

- Final Rule Signed: June 22, 2017
- Final Rule published: August 11, 2017
- Industry must report on the chemicals they manufactured, and may report on chemicals they processes, in previous 10 years
- Chemicals reported will be designated as active
- Chemicals not reported will be designated as inactive
- Industry must report on the chemicals designated as inactive when they restart or plan to restart commercial activities of that designated substance.

Reporting will help inform the chemicals EPA prioritizes for risk evaluation.
### Active / Inactive Inventory Notification Rule

#### Retrospective Reporting – NOA Form A

<table>
<thead>
<tr>
<th>Who reports?</th>
<th>Manufacturer / Importer (must), Processor (may)</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is reported</td>
<td>Chemical substance listed on TSCA inventory Chemical substances on the TSCA inventory that were in U.S. commerce for non-exempt purposes during 10 years before June 22, 2016</td>
</tr>
</tbody>
</table>

#### Future Reporting – NOA Form B

<table>
<thead>
<tr>
<th>Who reports?</th>
<th>Manufacturer, importer and processors (must)</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is reported</td>
<td>Chemical substances designated as “inactive” on the TSCA Inventory that are anticipated to be re-introduced into U.S. commerce for non-exempt purpose.</td>
</tr>
<tr>
<td>Reporting period</td>
<td>prior to re-introduction into U.S. commerce, but not more than 90 days</td>
</tr>
</tbody>
</table>
Amended TSCA

Prioritization and Risk Evaluation Rules

TCSA Inventory Substance designated as Active

TSCA Workplan

Prioritization

Substance Designated High-Priority

Substance Designated Low-Priority

Risk Evaluation

Risk Management

EPA determination “unreasonable risk”

EPA determination “no unreasonable risk”

Impose restrictions to eliminate unreasonable risk

Amended TSCA

Prioritization Rule

Final Rule Signed: June 22, 2017

High-priority substance: may present an unreasonable risk of injury to health or the environment due to potential hazard and potential route of exposure under the conditions of use (including an unreasonable risk to a “potentially exposed or susceptible subpopulation”)

Low-priority substance: does not meet the standard for high-priority, based on information sufficient to establish

Preference: TSCA Work Plan chemicals (2014 issue, 90 substances) (List of the substances to be further assessed EPA identified as a part of enhancement of managing existing chemicals)

Screening criteria: Hazard, Exposure, Persistence, Bioaccumulation, Toxicity, Cancer, etc.
Amended TSCA

Risk Evaluation Rule (Existing substance)

- Determine if a chemical presents an unreasonable risk of injury to health or the environment under condition of use
- Without consideration of cost or other non-risk factors
- Including unreasonable risk of potentially exposed or susceptible subpopulation determined to be relevant to the evaluation

Final Rule Signed: June 22, 2017
Substance to be evaluated:
  - High-priority substance
  - Work plan Initial 10 substances
  - Manufacture Request
Evaluation Period:
  - 3~3.5 years / substance

PBT substances on TSCA work plan: Fast-track process, use and exposure assessment required and no formal risk evaluation (unless manufacture requested)

- 1,4 Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster (HBCD)
- Methylene Chloride
- N-Methylphrolidone
- Pigment Violet 29
- Trichloroethylene
- Tetrachloroethylene

5 substances getting expedited action:
- Decabromodiphenyl ether (DecaBDE)
- Pentachlorothiophenol (PCTP)
- Phenol, isopropylated, phosphate (3:1)
- Hexachlorobutadine (HCBD)
- 2,4,6-Tris(tert-butyl) phenol
Amended TSCA

**Condition of Use**

The circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manifactured, processed, distributed in commerce, used, or disposed of.

- Generally uses that are legacy uses and intentional misuse are not included in the conditions of use

- Statutory language for scope “the Administrator expects to consider”
  - EPA may exclude from an individual risk evaluation some activities that are conditions of use (e.g. deminimis use that presents low risk)

A risk determination will be made for each EPA includes in the risk evaluation
**Amended TSCA**

**Evaluation of New Chemical Substance**

**EPA**
- is required to make an **affirmative findings** on new chemicals or significant new uses of existing chemicals before those chemicals being launched in the market
- to decide either of the followings by statute after 90 days evaluation period

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
</table>
| Present an unreasonable risk                        | Section 5(f) order, 6(a) proposed rule  
Restriction/prohibition of manufacturing, processing distribution or disposal |
| Insufficient information to permit a reasoned evaluation of the risk | Section 5(e) order  
Regulation pending more information  
Section 5(e) order – prohibits or limits manufacture, processing, distribution in commerce, use or disposal including test requirements |
| Due to lack of sufficient information, the manufacture, processing, distribution in commerce, use or disposal may present un unreasonable risk | Commercialization can commence after the determination is made, Section 5(g) – Statement in FR |
| Substance is or will be produced in substantial quantity and either enters or may enter the environment in substantial quantities, or there is or may be insignificant or substantial exposure of the substance | |
Amended TSCA

CBI (Confidential Business Information)

New requirement: Greater public access to critical chemical information
   EPA is required to review CBI claim if it is appropriate or not
   EPA is requested to make new CBI rule

All CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA --- See CBI Substantiation Template by EPA

- Sunset time: 10 years (can be extended)
- Review: New CBI claim – Chemical identity 100%
   Other information 25%

Unique Identifier is assigned to the chemical identity
   → Unique Identifier is applied to other information or submission
   → Ensure non-confidential information received by EPA identifies the chemical substance using unique identifier while protecting specific chemical identity information
**Fee Rule**

Note: Small Business – Revenue $91MM as average annual value over 3 years preceding the date of submission.

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee ($US)</th>
<th>Fee($US) Small Business</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SECTION 4</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Order</td>
<td>9,800.00</td>
<td>1,950.00</td>
</tr>
<tr>
<td>Test Rule</td>
<td>29,500.00</td>
<td>5,900.00</td>
</tr>
<tr>
<td>Enforceable Constant Agreement</td>
<td>22,800.00</td>
<td>4,600.00</td>
</tr>
<tr>
<td><strong>SECTION 5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMN, SNUN, MACA</td>
<td>16,000.00</td>
<td>2,800.00</td>
</tr>
<tr>
<td>LoREX, LVE, TME etc.</td>
<td>4,700.00</td>
<td>940.00</td>
</tr>
<tr>
<td><strong>SECTION 6</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPA-initiated</td>
<td>1,350,000.00</td>
<td>27,000.00</td>
</tr>
<tr>
<td>Manufacture-related (Work Plan)</td>
<td>1,300,000.00</td>
<td>1,300,000.00</td>
</tr>
<tr>
<td>Manufacture-related (non Work Plan)</td>
<td>2,600,000.00</td>
<td>2,600,000.00</td>
</tr>
</tbody>
</table>

**Prepublication Proposed Rule** : From fiscal year 2019 (October 1, 2018)

After publication on Federal Register, collection under new rule will commence.

Fees will be adjusted every three years if the amount received would be sufficient to cover 25% of the costs for TSCA 4,5 and 6.
Amended TSCA & Current Status

Evaluation at EPA --- PMN, MCANS, SNUNs, LVE & Other exemeptions

<table>
<thead>
<tr>
<th>Total Cases</th>
<th>1,894</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Review Completed</td>
<td>1,351</td>
</tr>
<tr>
<td>Cases Determined to be Invalid or Incomplete</td>
<td>91</td>
</tr>
<tr>
<td>Cases Under review as of April 10, 2018</td>
<td>452</td>
</tr>
</tbody>
</table>

PMN/MCAN/SNUM Review Completed

| Allowed to commercialize with out restrictions – Not likely to present unreasonable risk, TSCA 5(g) notice | 122 (≒20%) |
| Allowed to commercialize with restrictions | 341 (≒.54%) |
| - Insufficient information – TSCA 5(e) order & SNUR |
| - May present unreasonable risk – Exposure-based guidelines apply for production greater than 10t/year – TSCA 5(e) order & test at certain production volume |
| Not allowed to commercialize pending development of information | 3 |
| - May present unreasonable risk – TSCA5(e), test required before commercialization |
| - Insufficient information – TSCA 5(e) order, test before commercialization |
| Banned | 0 |
| - Will present unreasonable risk – TSCA 5(f), 5(f) order or 6)a rule & SNUR |
| Case withdrawn | 170 |
| Total | 636 |

LVE& LoREX Completed

| Exemption Granted | 562 (≒80%) |
| Exemption Denied | 120 |
| Withdrawn | 33 |
| Total | 715 |

NOC

| No received | 455 |

Period: June 22, 2016 – April 10, 2018

**SNUR**

One type of safety determination is that a chemical can be used safely for uses listed in the PMN but that this may not be true for other uses

→ EPA can allow that new chemical to become an existing chemical with limitations

A significant new use rule is a regulation that describes allowed uses of a new chemical and restrictions that manufacturers, importer or processors must follow as well as the reporting procedures they have to follow in case of using that chemical substance

→ Under New TSCA, understanding “SNUR” is extremely important

EPA review of new chemical substance = Affirmatively determine safety → EPA liable in the event that a chemical if found to be unsafe → EPA is being more cautious and only allowing uses and practices where they are comfortable safety can be assured → **SNUR more common**

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**Significant impact on business**
Amended TSCA & Current Status

How to face PMN review & SNUR

- Ensure all available information on a chemical (tests, literature, models, etc) and include it in a PMN and subsequent SNUN’s if any
- Be aware of EPA’s concerns about classes of chemicals
- Confirm your chemical does not included addressed concern in the initial PMN
- Consider available literature that addresses concerns and provide references to EPA as part of PMN
- Be aware what SNUR are and estimate potential impact on business
- Information sharing within supply chain and positive information supply to EPA
- Pre-submission consultation with EPA

Call us immediately!
We, Knoell Group will assist you on every TSCA notifications in perfect manner, from consultation, dossier preparation, submission to inventory listing of your substances.
Thank you so much to be with us today!!

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K. Maehara (Kmaeahra@knoell.com)