

# **3E Company Best Practices Web Seminar Series**

## **“Importing Products - TSCA Considerations”**

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## Jillaine Dellis, Vice President, Ariel Global Research & Operations

- Responsible for leading the company's Ariel Global Regulatory Information Decision Support Products business
- Brings 3E Company over 15 Years of regulatory compliance leadership
- Past Experience
  - Prior to 3E, she managed the Regulatory Compliance Department at S.C. Johnson
  - Responsible for global compliance of SCJ's Home Storage Business
  - Developed & Managed SCJ's global product safety, regulatory and environmental compliance assessment program
- Education
  - Marquette University, Bachelors of Science in Biomedical Engineering
  - Milwaukee School of Engineering, Master of Science

# Importing Products TSCA Considerations

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## TSCA

- Overview
- Import notification
- Inventory
- R&D exemption

## Toxic Substances Control Act

- Promulgated in 1976; an act of Congress
- Seeks to evaluate and prevent chemical human health and environmental risks before a chemical is introduced into commerce
- Authority granted to the EPA
  - Gather information about chemical substances
  - Evaluate and prevent risks associated with chemical substances
  - Control exposure by regulating chemical production, distribution and handling
- Activities impacted
  - Manufacture
  - Import
  - Processing
  - Distribution

## Requirements under TSCA

- Record-keeping
- Reporting
- Information gathering

## Civil and criminal penalties for TSCA violations

- Civil: fines = \$32,500/day/violation
- Criminal: imprisonment and/or fines

## TSCA Definition of chemical

Any organic or inorganic substance of a particular molecular identity including

- Any combination of substances occurring in whole or in part as a result of
  - a chemical reaction
  - occurring in nature
- Any element or uncombined radical

## Chemicals exempt from TSCA

- Tobacco
- Nuclear materials
- Firearms
- Pesticides
- Food
- Drugs
- Cosmetics

## Chemicals requiring special attention

- Mixtures
- Articles
- Polymers
- Pesticides (finished products)

EPA one agency of many imposing regulatory requirements on imported substances and substances introduced into commerce in the US, others include

- Secretary of Treasury, US Customs Services
- DOT
- CPSC
- OSHA

- Import equals manufacture
- Must certify
  - Shipment is subject to TSCA and complies with all applicable rules and orders (positive)
    - Chemicals
    - Mixtures
    - Samples
  - Shipment is not subject to TSCA (negative)
    - Pesticides; except when accompanied by EPA Form 3540-1
    - Nuclear materials
    - Food, Food Additives, Drugs, Cosmetics, or Medical Devices; except when accompanied by FDA form FD701
    - Firearms and ammunitions
- Exclusion
  - Articles
  - Tobacco

## Positive certification

“I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA”

## Negative certification

“I certify that all chemicals in this shipment are not subject to TSCA”

- May appear on an appropriate entry document
- May appear on the commercial invoice
- May appear on a separate attachment to either the entry or the invoice document
- May be signed by means of a facsimile
- Must be signed by the importer of record
- Must keep a copy of the certification along with other Customs documentation for five years

## Blanket Certification

- Used to cover several shipments of the same chemical within a one-year period
- Written on the letterhead of the importer
- Lists the product covered by name and Harmonized Tariff Schedule of the United States subheading number
- Identifies the foreign supplier by name and address
- Signed by an authorized official for the importer
- Filed with District Director covering the port of entry
- Commercial invoice must reference the certification

## Compliance with other sections of TSCA

- Importer must determine if the shipment contains any chemical substance or mixture regulated under TSCA Sections 5, 6 or 7
- Importer must comply with Sections 4, 5, 6, 7 and 8 with respect to the substances or mixtures in the shipment

## Chemicals imported in articles

Chemicals imported as part of an article and are not intended to be removed and have no commercial purpose separate from the article of which they are a part are exempt from import certification

- Exempt
  - Catalytic converter
- Not Exempt
  - Ink in a pen
  - Toner in a copy machine

## Detention

- Chemicals may be detained at port of entry if importer fails to certify compliance with TSCA or if shipment is believed to not be in compliance with TSCA
- Prompt notification is provided to both importer and EPA

## Examples of imported substances

- Finished product labeled for resale in the US
- Finished product imported in individual containers for labeling and then resale in the US
- Bulk finished product imported for filling finished product containers in the US
- Bulk chemical imported for production of finished product
- Sales samples imported for distribution to potential buyers
- Samples imported for R&D purposes

- No chemical can be introduced to commerce in the US unless the chemical is on TSCA inventory
- Non-confidential and confidential sections
  - Non-confidential - available through Ariel's WebInsight
  - Confidential – submit a *bona fide* intent to manufacture or import a substance

## Confidential Inventory

*Bona fide* intent to manufacture or import, include in writing:

- Specific chemical identity
- Signed statement of intent to manufacture or import
- Description of the research and development activities conducted
- For imported substances
  - How long the substance has been in commercial use outside the United States
  - Name of the country in which the substance has been commercially used
  - Whether the importer believes the substance has already been used commercially in any country for the same purpose or application
- Major intended applications or uses

## Confidential inventory

*Bona fide* intent to manufacture or import, include in writing:

- Infrared spectrum or alternative spectra or other data which identify the substance
- Estimated date (month/year) which the PMN will be submitted
- Address of the facility where the manufacture or processing will most likely occur
- For substances manufactured in the United States, the most probable manufacturing process used for commercial use
- For imported substances, how the submitter is most likely going to process or use the substance for commercial purposes

## Confidential inventory

Submitting a *bona fide* intent to manufacture or import

## Additional information

- The foreign supplier must supply directly to the EPA any information that is claimed confidential and not available to the submitter
- EPA will take no more than 30 days to review a *bona fide* intent to manufacture or import

- Chemicals added to inventory by
  - Submitting a Pre-Manufacture Notification (PMN) followed by
  - Submission of a Notice of Commencement (NOC) within 30 days of first importation or manufacture
- If only a PMN is submitted, the chemical will not be added to the inventory
- At least 90 days and up to 180 days to clear PMN process

- PMN includes
  - Chemical information
    - Identity
    - Impurities
    - Synonyms or trade names
    - Description of by-products
    - Amounts intended to be manufactured
    - Categories of use and related information
    - Process and exposure information

- PMN includes (cont.)
  - Test Data
    - Human health or environmental effects test data
    - Literature search on health, ecological, physical and chemical properties, environmental fate, monitoring data and other data related to human exposure or environmental release
  - Manufacturers/importers bear the responsibility of proving their chemical does not present any unreasonable risk to human health or the environment

## Exemptions

### **Application Required**

- Test Market Exemption Application (TMEA)
- Low Volume Exemption (LVE)
- Low Release/Low Exposure Exemption (LoREX)

### **No Application Required**

- Polymer Exemption
- R&D Exemption

## Exemptions - Test Market Exemption Application

- Intended for test marketing a chemical which is not on the inventory
- Demonstrate that no unreasonable risk to human health or the environment is present
- Much the same information as is required by the PMN
- 45 day review

## Exemptions – Low Volume Exemption (LVE)

- For quantities produced or imported of 10,000 kilograms or less annually
- Demonstrate that no unreasonable risk to human health or the environment is present
- More than one manufacturer may hold an LVE for the same substance
- LVE substances are not added to the inventory
- 30 day review

## Exemptions – Low Release/Low Exposure Exemption (LoREX)

- Independent of production volume
- Focus on release and exposure, not toxicity
- No exposure to consumers or the general public
- Worker exposure is adequately controlled
- Environmental releases are controlled and extremely low
  - 1 ppb for surface water concentration
  - No landfill disposal, unless demonstrated negligible ground-water migration potential
- 30 day review

## Exemptions - Polymer Exemption

- Eligible polymers
  - 1,000 to 10,000 daltons, restrictions on low molecular weight and reactive functional groups
  - 10,000+ daltons, restrictions on low molecular weight
  - No polymer which degrades, decomposes, or depolymerizes is eligible
  - International OECD definition of polymer applies
- No application required
- Recordkeeping requirements
- Annual report must be submitted
  - Number of exempt polymers
- Burden of ensuring eligibility is on the manufacturer

Small quantities of new chemicals used solely for R&D purposes

- Permissible (R&D)
  - Analysis
  - Physical characteristics
  - Performance
- Not Permissible (Test Market)
  - Customer acceptance
  - Probable demand in the marketplace
- Supervised by a technically qualified individual
- No general commercial use
- Evaluate potential risks and notify others of risks, if “prudent lab practices” not in place
- No evaluation or notification required if “prudent laboratory practices” are in place in the lab
- Notification that the substance is subject to R&D activities

## Recordkeeping requirements

- Prudent lab practices not in place
  - Information reviewed to determine risk
  - Documentation of the nature and method of risk notification
- Prudent lab practices are in place
  - Documentation of prudent lab practices
- Distribution of substance to other persons
  - Name and address of recipients of substance
  - Identity of substance
  - Amount distributed
  - Copies of written notification
    - substance is to be used for R&D purposes only
    - health risks
- Producers of 100+ kg/year
  - Record of identity of substance
  - Production volume
  - Disposition

- TSCA applies to all chemicals, not just toxic chemicals
- Imports require certification at the time of entry
- Import equals manufacture under TSCA
- Chemicals cannot be introduced to commerce in the US unless they are on the TSCA inventory; however, exemptions exist
- Inventory exemptions must be strictly followed, especially when no submission is required to enact the exemption

# Q&A

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