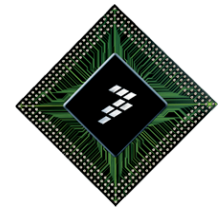


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CHEMICAL APPROVALS AND “TSCA”



Ed McCarthy
Corporate EHS Technical Support

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TOXIC SUBSTANCES CONTROL ACT (TSCA)

MAIN PROVISIONS

Chemical Controls - Manufacturing and Use Restrictions

Recordkeeping and Reporting Requirements

Enforcement - Civil and Criminal Penalties

TOXIC SUBSTANCES CONTROL ACT (TSCA)

Purpose: To protect human health and the environment from unreasonable risks presented by the manufacture and use of chemicals.

TSCA applies to almost all chemicals in commercial use.

Who must comply with TSCA?

- Manufacturers/Importers
- Processors
- Distributors
- Users
- Disposers

TSCA Inventory and New Chemical Review

All chemicals used in manufacturing must be on the TSCA Inventory

EPA maintains the TSCA Inventory of chemicals which have been approved for use

There are over 90,000 existing “chemical substances” on the TSCA Inventory

TSCA Inventory and New Chemical Review (cont.)

No new chemicals (not on the TSCA Inventory) can be used unless EPA is given 90 days advance notice. (Premanufacture notification or PMN)

EPA has 90 days to evaluate a chemical and decide whether to regulate it.

If the new chemical will present an unreasonable risk or if there is insufficient information, EPA can prohibit or limit use of the chemical.

TSCA Inventory and New Chemical Review (cont.)

Chemicals that are on the TSCA Inventory may be subject to a Significant New Use Rule (“SNUR”) limiting their use.

If a company wants to use a chemical for a use that EPA has determined is a significant new use, it must give EPA 90 days advance notice. (SNUN)

EPA then has 90 days to decide whether to restrict use of the chemical.

TSCA Inventory and New Chemical Review (cont.)

Some exemptions from the inventory and SNUR requirements include:

- Research and Development
 - use must be solely for R&D
 - limited to small quantities
 - handling must be supervised by a technically qualified individual
- Test Marketing
- Low Volume Exemptions
- Chemicals Imported in Articles
- LoREX (low release/exposure)

TSCA Inventory and New Chemical Review (cont.)

Using a chemical with a SNUR can present numerous requirements on the chemical user

Best known SNUR in the semiconductor industry is that for PFOS/PFAS

- Requirements are defined in § 721.9582 Certain perfluoroalkyl sulfonates
- Exempted uses include: use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photomicro lithography process to produce semiconductors or similar components of electronic or other miniaturized devices.
- As long as the chemicals are used as noted in exemption – there are no specific requirements

TSCA Inventory and New Chemical Review (cont.)

Other SNUR chemicals have been identified in the semiconductor and other industries

- Some photoresists components and encapsulant epoxy resins
- MSDS typically identifies the requirements for use, but not in all cases
- For clarity some MSDS specific wording is included on the next page

TSCA Inventory and New Chemical Review (cont.)

The following wording was taken directly from an MSDS:

TOXIC SUBSTANCES CONTROL ACT (TSCA): All of the compounds in this product are on the TSCA Inventory and/or are subject to a Low Volume Exemption. The bisphenol derivative is subject to the significant new use rule (40 CFR 721.1820). In accordance with federal regulations, this Photoresist shall be used only to industrially manufacture integrated circuits. In particular, this material shall not be distributed to any person, other than for disposal, until after it has been completely reacted. All users must utilize the worker protection measures and environmental release controls specified in this Material Safety Data Sheet. The significant new use rule codified in 40 CFR 721.1820 should be reviewed to ensure hazard communication programs, workplace practices and recordkeeping meet federal requirements. Use of this product without implementing the programs specified in 40 CFR 721.1820 shall be considered a significant new use. Acknowledgement of receipt of this Material Safety Data Sheet shall be considered acknowledgement that the user will comply with these requirements.

TSCA Inventory and New Chemical Review (cont.)

Some requirements from 40 CFR 721.1820

- Respirators (dusts & mists)
- “Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH- approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR part 11.”
 - Category 21C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters.
 - Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.
 - Category 21C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

TSCA Inventory and New Chemical Review (cont.)

Other specific requirements from 40 CFR 721.1820

- Hazard Communication
- Labels
- MSDSs
- Employee training and awareness
- Human health, environmental hazards, exposure and precautionary statements
 - Systemic effects - depression in body weight gain and blood effects.
 - Avoid breathing substance.
 - Avoid ingestion
 - Use respiratory protection (when in dust or mist form).
- Each human health or environmental hazard precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, “See MSDS for details.”

Imports and Exports Under TSCA

Importers

- Have all the duties of manufacturers (chemicals must be on the TSCA Inventory or be exempt, etc.), plus
- Must certify at the port of entry that either
 - The shipment is subject to TSCA and complies with all applicable rules and orders, or
 - it is not subject to TSCA.

Exporters

- Exporters of certain chemicals must notify EPA that it intends to export the chemicals. EPA will then notify the receiving country.

Other TSCA Provisions/Programs

Testing - EPA can require manufacturers and/or processors of chemicals to test chemicals for adverse health or environmental effects.

Regulation of Existing Chemicals - EPA has broad authority to regulate existing chemicals which present an unreasonable risk to health or the environment. Regulated chemicals include asbestos and PCBs.

Imminent Hazards - If a chemical presents an “imminent and unreasonable” risk of serious or widespread injury to health or the environment, EPA may seek injunctive and other relief, including seizure and condemnation of the chemical.

TSCA Recordkeeping and Reporting

TSCA recordkeeping and reporting requirements ensure that EPA will have access to new information on adverse health or environmental effects associated with chemicals.

EPA can track patterns of adverse reactions and limit or prohibit the manufacture, use, distribution and disposal of such chemicals.

TSCA Recordkeeping and Reporting (cont.)

Section 8(a) Reports

- Authorize EPA to require companies to maintain records and submit reports on production and use of chemicals.
- Preliminary Assessment Information Rule (PAIR) requires manufacturers and importers to complete a two-page form.
- CAIR provisions have been deleted

Section 8(b) Reports

- Inventory Updates for Manufacturers, Importers.
- Must submit production volume and exposure data every four (4) years if manufacturer or import 10,000 lbs or more of any chemical.

Health and Safety Studies (Section 8(d))

- Upon request, manufacturers, processors and distributors must submit to EPA health and safety studies conducted by, known to, or ascertainable by that person.

TSCA Recordkeeping and Reporting (cont.)

Records of Significant Adverse Reactions (Section 8(c))

- Manufacturers and certain processors and distributors must keep records of significant adverse reactions to health and the environment alleged to have been caused by a chemical substance or mixture.
- Allegations may be from “any source” including employees, customers, neighbors, etc. regardless of merit.
- Both written and oral allegations are included.
- Allegations must be kept on file. Only need to report if EPA requests them.
- Maintain employee reports for thirty (30) years, other for five (5) years.
- A series of identical or quite similar allegations about a particular substance may indicate a significant risk, triggering the substantial risk reporting requirements.

TSCA Recordkeeping and Reporting (cont.)

What is Section 8(c) “Allegation”?

Statement made without formal proof or regard for evidence that chemical substance or mixture caused significant adverse reaction to human health, environment.

Statement of belief is sufficient:

“I have a rash and think it is caused by . . .”

TSCA Recordkeeping and Reporting (cont.)

What is Section 8(c) “Significant Adverse Reaction”?

“Reactions that may indicate a substantial impairment of normal activities or long-lasting or irreversible damage to health or the environment.”

Examples

Health:	Cancer, Birth Defects, Rash
Environmental:	Groundwater Contamination Changes in Animal Behavior

Not “significant” if already Known Human Effect

Unless:

- More severe effect
- Shorter/less exposure causes effect
- Different exposure route

TSCA Recordkeeping and Reporting (cont.)

Open 8(c) File

Required elements of 8(c) filings:

- Signed
- Links cause and effect
- Fully describes adverse reaction

TSCA Recordkeeping and Reporting (cont.)

Substantial Risk Information(Section 8(e))

Manufacturers, processors and distributors of a chemical substance or mixture must report any information which they obtain that “reasonably supports the conclusion that the chemical substance or mixture presents a substantial risk of injury to health or the environment.”

Requires reporting “immediately”. Per EPA Guidance this means within 15 working days except for emergency incidents of environmental contamination.

Only new information needs to be reported, not information that merely corroborates well established adverse effects already documented in the scientific literature.

Applies to all substances (no R&D exemption.)

No 8(e) regulations - Only 1978 policy/guidance.

TSCA Recordkeeping and Reporting (cont.)

Section 8(e)

“Reasonable Supports Conclusion”:

As long as one (1) or more chemicals implicated
Even inconclusive evidence

“Substantial Risk”:

Factors

- Seriousness of effect
- Fact or probability of occurrence

TSCA Recordkeeping and Reporting (cont.)

Examples of 8(e) Substantial Risk Reports

Epidemiologic Studies with statistically significant health effect linked to chemical exposure

“Pattern” of serious health effects noted, common chemical use

Data indicating chemical spill into river caused fish-kill, plant life destruction

Groundwater contamination into aquifer, threat of cancer, birth defects to residents

Preliminary findings from toxicity testing programs, mice studies

Enforcement Under TSCA

EPA has authority to inspect facilities and to subpoena testimony and documents

Violations of TSCA can subject persons to civil penalties of up to \$27,500 per day

Knowing or willful for up to one year.

Production lines may be shut down until compliance is achieved.

