TSCA and TSCA Compliance

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The Environmental Protection Agency (EPA) was instructed under "The Toxic Substances Control Act" (TSCA) to take appropriate actions to ensure that new and existing chemicals do not "present an unreasonable risk of injury to health or the environment." It is intended that manufacturers and importers assume responsibility for providing data on the health and environmental effects of chemical substances and that the Administrator of the EPA have adequate authority to regulate those chemicals. TSCA is also intended to fill the gaps among the previously enacted environmental statutes.

The 1985 TSCA Chemical Substance Inventory contained over 63,000 chemical substances manufactured since 1975. The 1990 supplement contained an additional 5,000 materials. TSCA has been codified in Title 40 of the Code of Federal Regulations (CFR).

TSCA regulates all chemical substances and any isolated chemical intermediates used in their preparation with the following exceptions as noted in TSCA Section 3:

- Mixtures (of chemicals not formed by a chemical reaction)
- Pesticides as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Tobacco or tobacco products
- Nuclear materials as defined in the Atomic Energy Act
- Articles subject to Section 4181 of the IRS Code (firearms, shells, etc.)
- *Any food, food additive, drug, cosmetic or device when manufactured, processed or distributed in commerce as a food, food additive, drug or cosmetic device. Additionally, those intermediates intended solely for use in foods, food additives, drugs, cosmetics or cosmetic devices are also excluded from regulation under TSCA. FDA considers these intermediates to be integral components of the materials they are used to make (42 FR 64,586, Comment 41).*

Since chemicals used in the flavor and fragrance industry seem to be covered by the Federal Food, Drug and Cosmetics Act (FFDCA) as foods and cosmetics or their ingredients, why should we be concerned with TSCA?

FFDCA covers any food, food additive, drug, cosmetic or device (as defined in Section 201 of FFDCA) when manufactured, processed or distributed in commerce for use as a food, food additive, drug, cosmetic or device. *Not* included are soaps, detergents, air fresheners, etc. These applica-

CAIR — Comprehensive Assessment Information Rule
CAS # — Chemical Abstracts Service Number
CFR — Code of Federal Regulations
EPA — Environmental Protection Agency
FDA — Food and Drug Administration
FFDCA — Federal Food Drug and Cosmetics Act
FIFRA — Federal Insecticide, Fungicide and Rodenticide Act
IUR — Inventory Update Rule
LVE — Low volume exemption
NOC — Notice of Commencement
PAIR — Preliminary Assessment Information Rule
PMN — Premanufacture Notification
R&D — Research and Development
SNUN — Significant New Use Notice
SNUR — Significant New Use Rules
TME — Test Marketing Exemption
TSCA — The Toxic Substances Control Act

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tions are regulated by TSCA (42 FR 64,586, Comment 42).

Applicability—Who Must Report Under TSCA?

Anyone who intends to manufacture or import a new chemical substance subject to the act for commercial purposes must report under Section 5 of TSCA. Only a manufacturer that is incorporated or licensed to do business in the US may submit a Premanufacture Notification (PMN). Importers are included as manufacturers.

Is an Item Already on the TSCA Inventory?

When evaluating the status of a chemical, one must first determine whether the substance is on the TSCA inventory. The most common place to look is in the published inventory and its 1990 supplement which are available from the Superintendent of Documents, US Government Printing Office, Washington DC. Alternatively, the non-confidential inventory is available on computer tape and via a number of on-line database services such as Dialog or STN International. If the item is not on a published inventory, it may have been submitted recently, or it may be on the *confidential* inventory.

The existence of a Chemical Abstracts Service number (CAS#) for a substance ***cannot*** *be interpreted to mean that the material is listed on the TSCA inventory.* The CAS publishes abstracts of scientific and technical papers containing new information of chemical interest. These abstracts may also include new information found in chemical patent literature. In conjunction with the publication of new information, CAS Registry Numbers are assigned for new chemical substances entered into the CAS Chemical Registry System. Each CAS number designates only one chemical substance in terms of atoms, valence bonds and, to the extent identified, stereochemistry.

It is through this sequential numbering of new chemical substances published in the chemical literature that CAS numbers are determined and established. Chemicals enumerated with CAS numbers from the literature may or may not have a commercial use. Only non-excluded chemicals used in commerce may be listed on the TSCA inventory. Thus the existence of a CAS number for a substance cannot be interpreted to mean that the material is listed on the TSCA inventory. Inventory corrections may be used to place the most accurate CAS number on the TSCA inventory.

Bona Fide Search of the TSCA Inventory 40 CFR 720.25: The TSCA Inventory includes both Public and Confidential Inventories. The EPA will search these inventories when an applicant submits a request for a bona fide inventory search. A bona fide search request includes:

- Specific chemical identity or manufacturing process
- A signed statement that the person intends to manufacture or import for commercial purposes
- A description of R&D activities and the purpose of manufacture or import (identifies a significant or new use)
- Elemental analysis
- X-ray diffraction pattern, infrared spectrum or mass spectrum.

Registration of New Chemical Substances

Items NOT subject to Premanufacture Notification (PMNs) 40 CFR 720.30:

- Chemicals that are not "chemical substances" (mixture, pesticide, tobacco, etc.)
- Mixtures
- R&D chemicals
- New chemicals made for test-marketing purposes under an exemption
- New chemicals manufactured solely for export (Isolated intermediates made and consumed in the manufacture of the export chemical are **not** exempt.)
- Special exemption from the Administrator, Section 5(h)(4)
- Byproducts—burned as fuel, disposed of as waste material
- Impurities
- Byproducts not used for commercial purposes
- Incidental reaction products
- Incidental products formed during storage/disposal
- Chemical substances resulting from reactions that occur on the end use of another item
- Naturally occurring chemical substances (as defined under TSCA)
- Nonisolated intermediates—intermediates that are not intentionally removed from the equipment in which they are manufactured. (If the contents of a reactor are removed for work-up, it has been isolated. Transfer from one reactor to another is isolation.)

TSCA Section 5 - Premanufacturing Notifications and Exemptions

TSCA compliance may be obtained by several mechanisms, premanufacture notification (PMN), low volume exemption (LVE) or polymer exemption application.

Premanufacture Notification (PMN) 40 CFR 720: PMNs must be submitted to the EPA at least 90 days before manufacture or import of a new chemical substance for commercial purposes is to occur. There is a fee for filing PMNs:

- $100 per PMN for small companies (defined at 40 CFR 700.43)
- $2500 for other than small companies
- $1000 for each "intermediate" involved in a synthetic sequence.

The fee is submitted at the same time as the PMN, but does not accompany the PMN. The PMN fee is sent separately to the EPA HQ Accounting Office in Pittsburgh, Pennsylvania. The six-digit "TS" number on the PMN and certified check link the two together.

Elements of a PMN (EPA Form 7710-25 must be used):

- Chemical identity information
- Production or import volume information
- Description of use
- Industrial sites controlled by submitter and others
- Pollution prevention information
- Test data: health and environmental in your possession or as required by the EPA during the review process
- A sanitized version if confidentiality is required.

The PMN review period is 90 days. The EPA will notify, in writing, of the date for which the PMN was received at the EPA (clock starts ticking), and will assign a PMN Number. The EPA's official close of review periods are also published in the *Federal Register* along with other non-confidential information.

The review period does not begin until the EPA has received a **complete submission.** The submitter will be notified within 30 days of receipt of an incomplete submission. The review period may be extended by the EPA if additional information is required.

A submitter may withdraw a PMN during the review period. Withdrawal must be in writing. It is effective from the date received by the EPA.

Notice of Commencement (NOC) of Manufacture or Import: Upon expiration of the 90-day review period, nonexempt manufacture or importation may commence. No later than 30 days after the start of such import or manufacture from the last "isolated" intermediate, a NOC must be sent to the EPA. Once the EPA receives the NOC, the item is added to the TSCA inventory. It is important to note that a NOC must not be filed until after the first nonexempt manufacture or import following the close of the 90-day review period. The first three years of production records must be retained for five years. Any claims of confidentiality indicated on the PMN must be substantiated when the NOC is sent in to the EPA (40 CFR 720.85(b)).

Low Volume Exemption (LVE) 40 CFR 723.50: If a company anticipates production of less than 1,000 kg/year of a chemical substance for a TSCA-subject use, a low-volume exemption may be requested. An LVE may be granted to only one company (the first - subsequent manu-

facturers must file PMNs), costs nothing and may require less data and paperwork than a full PMN. After the LVE is received at the EPA, the manufacture or import for commercial purposes may begin after a 21-day waiting period. The EPA will notify you by mail of the date on which it receives the LVE (21-day clock starts ticking) and a case number will be assigned. The EPA may suspend the review period should additional information be required.

Production records must be kept so as not to exceed the 1,000 kg/year limit. These records must be kept for five years on a rolling basis. Should the 1,000 kg/year limit be met in any one year, a PMN will need to be filed at least 90 days before the 1,000 kg/year quantity is exceeded. Years are based on a 12-month period, not calendar year! Change of manufacturing site or use requires submission of a new notice. For LVEs a NOC to manufacture is *not* filed. Therefore, the item is *not* placed on the TSCA inventory. However, though "not on the inventory," the manufacture or import is in compliance with TSCA, and may be so certified to customers.

Elements of an LVE are:

- Chemical identity information
- Description of use
- Sites of manufacture
- Test data: health and environmental data in your possession
- Exposure controls in use
- Certification
- A sanitized version if confidentiality is required
- (Optionally, PMN Form 7710-25 may be used for LVEs).

Polymer Exemption 40 CFR 723.250: The polymer exemption is available for polymers that will not cause unreasonable risk of injury to human health or the environment. Polymers must not be chemically active or bioavailable.

Elements of a Polymer Exemption are:

- EPA Form 7710-25 must be used
- Name of manufacturer
- Site of manufacture
- Chemical identity
- Production use and volume
- Molecular weight and chemical data include: Residual monomer and other reactants. One is then bound to those quantities. If residual levels are exceeded, another exemption or PMN must be submitted. PMN and polymer exemption may be submitted simultaneously. However, separate notices and fees must be submitted for each type of notice.

Polymer exemption review period is 21 days.

The following requirements apply:

- Material must meet the definition of a polymer (40 CFR 723.2250(b)(11))
- Polymer must not come from any of seven classes of ineligible polymers (40 CFR 723.250(d)(1-7))
- Polymer molecular weight must be greater than 1,000 or be a polyester made from a specified list of reactants (40 CFR 723.250(e)(1) & (2)).

Unlike the LVE, materials subject to the polymer exemption are added to the TSCA inventory and an NOC must be submitted when commercial production starts. Polymer exemption contains a five-year recordkeeping requirement.

Exemptions to PMN Requirements

Research and Development (40 CFR 720.36) and Test Marketing (40 CFR 720.38)

Research and Development: Section 5(h)(3) exempts substances manufactured in small quantities solely for R&D purposes which is, for scientific experimentation or analysis, chemical research on or analysis of the substance. General distribution of a chemical substance to consumers does **not** constitute R&D. However, a company **may** sell an R&D chemical for R&D purposes. These activities focus on process development, physical characteristics, product performance or analysis.

R&D requirements and recordkeeping include:

- Small production (relative to commercial situation)
- Supervision by technically qualified individual
- No general commercial use
- Evaluation of risk
- Information in its possession/control regarding significant adverse effects
- Information supplied by manufacturer or importer regarding health risks
- Health and environmental effects data
- Information on health effects which accompany any EPA rule
- Notification of risk (Manufacturer must notify non-employees who receive R&D material in writing of risks associated with R&D materials. Employees must be notified by appropriate means.)
- Notification of the requirement that the substance is to be used only for R&D.

Successful R&D may eventually lead to commercial activity. The decision to pursue commercial activity typically leads to submission of a PMN. Surplus R&D material may be sold after expiration of the 90-day PMN review period, and customers may be informed that commercial use of the product is acceptable. However, sale of surplus R&D material does **not** constitute commercial manufacture and an NOC may **not** be submitted. The NOC should only be submitted after first commercial manufacture/import following the 90-day review period.

For recordkeeping, manufacturers distributing R&D materials to persons not in their employ must record the names and addresses of those that receive the substance. Record the identity of the substance, amount, copies of written notification. Records must be kept for five years.

Test Marketing Exemption (TME) Section 5(h)(1): Available upon application, the TME allows the EPA to exempt a manufacturer or processor from PMN requirements for the manufacture or processing of a material for the purposes of test marketing.

The EPA must determine that the test marketing of the material will not present an unreasonable risk of injury to health or to environment.

The applicant must provide:

- All existing data (health and safety)
- Quantities to be manufactured/distributed
- Number of potential customers
- Exposure information (routes, duration, etc.)
- Time period of test.

Objectives of test marketing are to evaluate customer acceptance of the substance and evaluate demand.

The EPA will either approve or deny the TME within 45 days of its receipt. Results will be published in the *Federal Register.* The EPA Form 7710-25 should be used.

Regulation of Chemicals and Chemical Uses

Consent Orders, Section 5(e): Under Section 5(e), the EPA can issue an administrative order regulating a new chemical if the Agency finds:

- It has insufficient information for risk evaluation
- The chemical may present unreasonable risk of injury to health or environment
- The chemical will be produced in substantial quantities with substantial quantities entering the environment or there is substantial or significant human exposure to the quantities produced.

The EPA views any deviation from any term of a TSCA 5(e) Consent Order as an extremely serious matter and vigorous enforcement action will result.

A Section 5(e) order can prohibit or place limitations on manufacture, distribution, use and disposal of chemicals until the EPA is provided with adequate information for risk evaluation. Consent orders do not affect or limit manufacture for exempt uses such as R&D, export only or regulation under another statutory authority (FFDCA, FIFRA, etc.)

provided the exempt uses are the sole uses occurring for that chemical.

The EPA may establish specific limitations on the PMN material:

- Limits on final product
- Require personal protective equipment
- Require engineering controls
- Labeling
- Notification to customers of these limits
- Quantities produced while awaiting toxicity testing results.

Taking effect on the expiration of the 90-day PMN review period, Section 5(e) consent orders affect only the submitter of the PMN. All other manufacturers are not bound to the limits of the order. To overcome this inequity, the EPA (possibly negotiated by the PMN submitter) may issue a Significant New Use Rule (SNUR) to apply the same Section 5(e) restrictions to all domestic manufacturers. Section 5(e) orders limiting the manufacturing process may provide an advantage to importers because order restrictions would not apply to foreign manufacturing processes.

Significant New Use Rules (SNUR) 40 CFR 721: When a PMN is submitted, the EPA reviews potential for risk of injury to health and environment based in part upon the intended use as identified on the PMN. After a substance is listed on the inventory, the PMN submitter or others may identify uses for the substance that were not indicated on the PMN. These new uses of the substance, increased production, or different type or extent of exposure, may increase environmental or human exposure.

In an effort to control this new exposure or use, the EPA may determine by Rule, that a particular use of a chemical, already on the inventory, would be a significant new use. The EPA would issue a SNUR.

Anyone that wishes to make a substance for a significant new use, as determined by the EPA, must submit a PMN 90 days before manufacture for that use. In this case the PMN notice is referred to as a Significant New Use Notice (SNUN).

To address unreasonable risk of injury to health or environment, TSCA Section 5(f) Orders allow the EPA to issue an immediate proposed rule to control, restrict or prohibit manufacture, import, process, distribution or use of a chemical in advance of rulemaking under Section 6.

TSCA Section 8 - Reporting and Retention of Information

TSCA Section 8(a) - Reports: The EPA may require manufacturers or processors of chemical substances to maintain records and submit to the Administrator such reports as the Administrator may reasonably require. Records are to include: chemical identity and name, use, quantities produced or processed, identification of byproducts, existing data on environmental and health effects, and the number of individuals that may contact the chemical. Small manufacturers/processors are exempt.

Inventory Update Rule (IUR) requires that manufacturers and importers report, every four years, information on chemical identity, production volume, plant site and site limited status on chemicals listed on the TSCA inventory produced or imported in quantities of 10,000 pounds or more at any single site.

Preliminary Assessment Information Rule (PAIR) is a model rule intended to gather preliminary exposure data so that the Agency can set priorities for further testing of chemi-

cals on its master list based on actual or potential toxicity. The list of chemicals can be found at 40 CFR 712.30. Additions to the list are made through notice and comment rulemaking. A one-time reporting requirement, manufacturers and importers must report on each listed chemical manufactured or imported during the reporting period for the substance as provided in the rule. Processors are not subject to PAIR.

The following are exempt from reporting under PAIR:

- Manufacture/import for R&D
- Manufacture/import less than 500 kg at a single site
- Small manufacturer/importer (actual annual sales from all sites by foreign/domestic parent below $30 million and produced less than 45,400 kg of the listed chemical at the plant site)
- Chemical was non-isolated intermediate, or impurity or product under certain conditions.

Comprehensive Assessment Information Rule (CAIR) 40 CFR 704 Subpart C&D requires CAIR reports that are used by the agency to elicit information on chemical substances through the use of a single form.

- Covers manufacturers, importers and processors.
- Addresses 19 chemicals (40 CFR 704 Subpart D).
- Gathers information through responses to selected questions on a 141-page form.
- No minimum threshold value.
- Claims of confidentiality are to be substantiated at time of filing.

TSCA Section 8(b) - Inventory: The Administrator is charged with compiling, updating and publishing a list of each chemical substance manufactured or processed in the United States. Not included are substances produced in small quantities for R&D, polymers, naturals, inorganics and microorganisms. The substance is added to the inventory when the NOC is filed.

TSCA Section 8(c) - Recordkeeping: Manufacturers, processors and distributors are required to maintain records of adverse reactions to health or the environment. Adverse health reactions may be reported by employees using the item, customers, neighboring company employees or "any source." Records of employee allegations must be kept for 30 years, all others for five years. Records must be provided to the EPA upon request.

TSCA Section 8(d) - Health and Safety Studies: Manufacturers, processors and distributors are required to submit, upon request by the Administrator, lists and copies of health and safety studies conducted or initiated by, known to, or reasonably ascertainable by such person.

TSCA Section 8(e) - Reporting: Manufacturers, processors and distributors are required to notify the EPA of any information not already in the EPA's possession concerning substantial risk of injury to health or environment.

Substantial risk information:

- Pertains to chemicals having a TSCA use or application
- Reporting of substantial risk information is **self actuating,** requiring manufacturers, processors, and distributors to report based on a **subjective** evaluation of the risk information. *Any* information that **reasonably** supports a conclusion of substantial risk posed by a chemical is reportable.
- Reports are due to the EPA within 15 days of receipt of substantial risk information.
- There is no exemption for intermediates including

non-isolated intermediates and pesticide intermediates.

- There is no polymer, export, nor R&D exemption for reporting of substantial risk.
- There is no low-volume exemption.
- There is no small business exemption.

Reporting requirements under Section 8(e):

- Pertains only to information of which the EPA has not been adequately informed (difficult to interpret).
- Sent by method of verifiable receipt (Certified/ Registered mail).
- Statement that submission is under Section 8(e) of TSCA
- Submitter identity, title, phone number, address
- Chemical identity
- Summary of adverse effects
- Source of data
- Emergency incidents
- Confidentiality claim
- Manufacturer, importer, processor and distributor is said to have obtained 8(e) information at the time an officer or employee capable of appreciating the information first possesses or knows of such information.
- There is no need to report if you don't manufacture, distribute, import or process.
- There is no need to report if you did, but no longer manufacture, import, distribute or process.

TSCA Section 12 - Exports

TSCA Section 12 has the following stipulations:

- Contract manufacturing for export is allowed as long as the material is "manufactured solely for export."
- Export substances are exempt from some provisions of TSCA (i.e., PMNs). However, Section 8 still applies.
- The export exemption does not apply if the Administrator feels the substance may cause harm to health or the environment.
- *Intermediates made and consumed in the manufacture of export substances are not exempt.*
- Export chemicals must be labeled "For Export Only."
- Section 12(b): Exporters must notify the EPA before shipment abroad if the material requires test data under Section 4 (testing of chemical substances and mixtures) or 5(b)(submission of test data), or if regulatory action has been proposed or taken under Section 5 (manufacturing and process notices) or 6 (regulation of hazardous chemical substances and mixtures), or an action is pending or relief granted under Section 5 or 7 (imminent hazards).

TSCA Section 13 - Importation and Certification

An importer is required to certify to US Customs Service that an imported item is either in compliance with the TSCA or excluded from the TSCA for a specified reason (covered by FFDCA, FIFRA, etc.). This is codified at 19 CFR 12.118 through 12.127 and 127.28.

Compliance requires a "positive certification." Exclusion requires either a "negative certification" or "no certification." The exact wording of the certification is very important. See 40 CFR 707.20(2)(i) and 40 CFR 707.20 (2)(ii).

A negative TSCA certification is not required if a positive certification is required under another statutory authority. (FFDCA requires a separate positive certification.) For items not requiring a positive certification under another statutory authority (FIFRA, nuclear source material, firearms and ammunitions) a negative TSCA certification is required.

Conclusion

Although many uses of chemical substances by our industry are regulated under the FFDCA, most of these materials also have potential applications requiring some form of TSCA compliance. Fines for non-compliance are substantial. Fines in the millions of dollar range are not uncommon. Failure to comply with the PMN provisions may result in fines according to the number of times the provision was violated, the volume of material involved, and potential for harm to the environment. "False" NOCs are a $25,000 violation and occur when a NOC is submitted to the Agency and production (non-exempt commercial production) never occurs.

The EPA has published a TSCA Section 5 Enforcement Response Policy (Office of Compliance Monitoring) detailing enforcement procedures and penalties. Violations are categorized into a penalty matrix of circumstance (high, medium, low) and extent (major, significant, minor). Penalty amounts for violators will be reduced (up to 50%) for voluntary disclosure. Additionally, the EPA has separate Enforcement Response Policies for each Section of the TSCA. Section 8(e) reporting violations can result in fines of up to $25,000/day, so one must carefully consider what data "reasonably supports an interpretation of substantial risk of injury to health or environment."

The EPA provides assistance to industry should questions arise. The TSCA "Hotline" number is 202/554-1404 or fax 202/554-5603.

Reference

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