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TSCA Chemical Recordkeeping and Reporting

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It's a Chemical World

Chemicals are everywhere. No matter what you do, whether manufacturing, research, engineering and consulting, maintenance and support, or even environmental remediation, you will be in contact with chemicals. One of the more significant environmental laws addressing chemicals is the Toxic Substances Control Act (TSCA) enacted in 1976. The law compels manufacturers, importers, processors, and in some instances users of chemical substances to have knowledge of their chemical substances. Much of the TSCA regulations center around paperwork. It is this paperwork that informs EPA about the potential risks of chemicals to human health and the environment. Without this information, the ability to effectively regulate or restrict the manufacturing, processing, or use of chemicals is lost until damage or harm has occurred. EPA values this reporting and recordkeeping so much so that penalties for non-compliance of these administrative rules typically carry some of the highest fines. In 2006 one chemical company paid approximately $1.5 MM for failing to report to EPA information about the manufacture of new chemicals. Another company paid $10.25 MM, the highest civil administrative penalty issued by EPA, for failing to report substantial risk information to EPA regarding a well distributed chemical substance.[1]

In many industrial settings it commonly falls to the SH&E professional to be the begrudging TSCA coordinator for their facility. The SH&E professional typically has a good handle on the chemical-specific management standards under TSCA, such as those for poly-chlorinated bi-phenyls (PCBs). However, many are uncertain, or unaware of the vast recordkeeping requirements. In addition, as the business world becomes more global, chemical substance reporting is beginning to extend beyond the borders of the US. Programs, such as REACH, place a greater responsibility on facilities to not only have a detailed understanding of the chemical constituents in their products and processes, but to provide that information to government entities.

The key to successful compliance is the implementation of a comprehensive constituents management system. The SH&E manager and organizations that invest in thoroughly knowing all

[1] Enforcement Report, FY2006, U.S. EPA

of their constituents and have control over what comes into their sphere of management control will be in the best position to assure that their TSCA obligations have been satisfied.

The following is intended to provide the SH&E manager with an awareness of the TSCA regulatory landscape.

TSCA: The Core System

Overview

Prior to the enactment of the Toxic Substances Control Act in 1976, knowledge of potential risks to human health and the environment from specific chemicals was generally not known until well after manufacturing and distribution in commerce. In the early 1970s the EPA was becoming increasingly aware of the risks of chemical substances such as poly-chlorinated bi-phenyls, vinyl chloride, heavy metals, and other substances. In a 1971 report to Congress, the Council on Environmental Quality noted a, "high priority need for a program of testing and control of toxic substances.[2] Based on the risks to human health and the environment associated with an increasingly large number of chemical substances Congress sought to implement an upstream process to learn about the hazards of chemical substances before their manufacture and introduction into commerce. In the Act, Congress stated that, "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and the development of such data should be the responsibility of those who manufacture and those that process such chemical substances and mixtures." [TSCA §2(b)(1), emphasis added]

"Chemical Substance"

TSCA is often labeled with the moniker, "the 800-pound gorilla," because the statute applies, in general to any "chemical substance." The Act purposely defines this term broadly as, "any organic or inorganic substances of a particular molecular identity." [TSCA §3(2)] In other words, if you draw the molecule, it is regulated! That does not leave too many things from TSCA's grip. The term includes naturally occurring chemical substances and even elements.

There are exceptions. These generally fall into two categories – those that are chemical substances, but are regulated in a similar way under other programs, and those that are mixtures. The first category excludes substances such as:

- Pesticides – which were already regulated under a similarly comprehensive program under the Federal Insecticide fungicide and Rodenticide Act of 1975
- Tobacco and tobacco products
- Various radioactive substances
- Food, food additives, and cosmetics

Mixtures

TSCA defines mixtures as a, "combination of two or more chemical substances." Examples of mixtures can include what EPA calls "formulated mixtures" which are blends of two or more

[2] *Toxic Substance*s, Council on Environmental Quality, April 1971, reprinted in *History of the Toxic Substances Control Act 760*, House Committee on Interstate and Foreign Commerce, 94th Congress, 1976

individual chemical substances that do not result in a chemical reaction (e.g., petroleum streams, gasoline blends, multi-nutrient fertilizers, etc.). There are also "statutory mixtures" that include substances formed during certain manufacturing activities (e.g., inorganic glasses, ceramics, and cements). In general, the constituents that make up the mixtures are still chemical substances and therefore subject to requirements related to chemical substances (e.g., pre-manufacture notices and inventory update reporting).

There are instances where mixtures are not mixtures, at least from a TSCA standpoint. Combinations of chemical substances that result from a chemical reaction are considered chemical substances, under TSCA, and not mixtures. Also, naturally occurring substances such as crude oil, ore, rock, natural gas, and minerals are considered chemical substances under TSCA.

Just because you may have a mixture as defined by TSCA, does not mean that you are excluded from TSCA requirements. Although mixtures would be excluded from requirements such as pre-manufacturing notifications (remember the constituents would still be regulated here), mixtures can still be subject to testing requirements, specific management standards, or reporting requirements [TSCA §§4, 6, and 8].

Articles

The TSCA rules define "articles" as items that are manufactured to a particular shape or design, have an end use dependant on the shape or design, and do not change their chemical composition through their end use [40 CFR 710.3(d)]. The TSCA rules typically exclude the chemical substances in articles from the recordkeeping and reporting requirements; however certain articles can still be regulated under specific management standards (e.g., PCB transformers under 40 CFR 761).

The Inventory

A central component to TSCA was the requirement for EPA to create and maintain a list of every "chemical substance" manufactured in the United States. This list, which was originally created in 1978 with approximately 58,000 substances, is dependent on the manufacturers notifying EPA of the chemical substances they are manufacturing.

Since the original list was published, the inventory has grown to nearly 80,000 chemical substances. The EPA has two specific rules applicable to manufacturers to assure that the inventory of chemical substances is maintained.

Inventory Update Reporting

The inventory update rule (IUR), at 40 CFR Part 710, applies to manufacturers of chemical substance that are already on EPA's inventory. Any site that manufactures $\geq$ 25,000 pounds of a listed chemical during the reporting year, must submit the following information specific to that chemical substance:

- Total volume manufactured (including importing) at the site during the reporting year
- Number of workers exposed
- Maximum concentrations and physical forms for chemical substances sent off site

This information is submitted on a standardized form (Form U) once every five years. The next reporting year is 2010 with reports due between June 1 and September 30, 2011. Since this is a chemical-specific requirement, the site must be prepared to track the manufacturing quantities throughout the site for *each* chemical substance. There are exclusions in Part 710 for:

- Small quantities manufactured for research and development
- Small manufacturers
- Certain polymers and inorganic substances
- Microorganisms
- Naturally occurring substances (e.g., crude oil)

New Chemical Reporting

An industrialized country, such as the United States, will constantly have manufacturers producing new chemical substances. TSCA requires that EPA be aware of these chemicals. The pre-manufacturing rules at 40 CFR Part 720, apply to persons that manufacture chemical substances that are not on EPA's chemical substance inventory. According to the requirements at Part 720 the manufacturer must submit a pre-manufacture notice (PMN) at least 90 days *before* intending to manufacture this new (i.e., not listed on the inventory) chemical substance.

One of the challenges with this rule is that the many of the chemicals listed on the inventory are listed under a generic name (this is due to trade secret protections offered under the Act). The only person that has access to the entire list is the EPA. As such, any person that manufactures a new chemical substance is compelled to submit a notice of *bona-fide* intent to manufacture that chemical substance. This of course further delays the ability to manufacture the chemical substance. If a PMN is required, the EPA will request information, on a standardized form (EPA Form 7710-25), specific to the manufacturer and chemical substance. During the 90 days, EPA evaluates this proposed new substance with one of three outcomes:

- Approval to manufacture – triggering yet another report called a Notice of Commencement of Manufacturing (NOCM, EPA Form 7710-56)
- Request for more information, including testing – this will suspend the 90-day period until the additional data is received by EPA
- Restricted manufacturing – this will be specified under a site/manufacturer-specific consent order [TSCA §5(e)]

There are exceptions provided for:

- Small quantities for research and development
- Test market exemptions (TME)
- Low volume or low release/exposure (LVE and LoREX)
- Substances produced solely for export

Manufacturers

As with just about every regulation, nothing is what it seems on the surface. Much of the TSCA recordkeeping requirements, including the inventory reporting rules apply to the manufacturers of the chemical substance. TSCA defines manufacturers as those that, "*import* into the customs

territory of the United States…produce, or manufacture." [TSCA §3(7)] The customs territory of the US includes the 50 states, Washington, D.C., and Puerto Rico [general note 2, Harmonized Tariff Schedule of the United States]. So any person that imports a chemical substance, including constituents in a mixture that is imported, is a manufacturer under TSCA. Any recordkeeping and reporting rules applicable to manufacturers would also apply to those importers.

This is the very issue that once snagged a client of ours. A manufacturing facility in the United States had an affiliate site in Europe send them a shipment of new paint for their product line. The shipment was held up by Customs when it was discovered that certain paperwork was missing. Although paint is a mixture, the individual constituents in the paint are still regulated as chemical substances under TSCA. Upon investigation, it was discovered that a few of the constituents were not on the TSCA inventory. Since the U.S. site did not submit a pre-manufacture notice to EPA 90 days before importing they were in violation of the act and paid a significant civil penalty. They learned the hard way that constituents management has to evaluate all source of entry, including those outside our borders.

Significant New Use Reporting

Under TSCA §5(e), the EPA can establish a consent order with the manufacturer of a new chemical substance. This order can restrict manufacturing, processing, use or disposal. However, these orders only apply to the specific manufacturer that submitted the pre-manufacture notice. In some instances the EPA extends the same restrictions to subsequent manufacturers. This is done through the Significant New Use Reporting rules at 40 CFR Part 721. The rule identifies a specific list of chemical substances [40 CFR 721, Subpart E]. For each, the EPA identifies specific conditions that qualify as significant new uses. These may include:

- Uses that require specified personal protection;
- Uses where a specified hazard communication program has not been developed;
- Specific types of commercial or consumer uses;
- Uses resulting in incineration or land disposal; and/or
- Uses resulting in release to water.

Any person that intends to engage in a significant new use, must submit a Significant New Use Notice (SNUN) at least 90 days prior. The process is similar to the PMN process, including the use of the same form, EPA Form 7710-25.

Chemical Reporting

Beyond the TSCA inventory rules; there are several reporting rules that apply to various chemical substances.

Specific Chemicals [Part 704]

Manufacturers, importers, and processors of chemical substances and mixtures identified in 40 CFR 704, Subpart B are required to comply with the various reporting and recordkeeping requirements for the substances identified. The following are included among those specific substances identified in Part 704:

- 11-Aminoundecanoic acid;
- P-TBBA, P-TBT, P-TBB;
- Chlorinated naphthalenes;
- Chlorinated terphenyl;
- Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis-(EDTMPA) and its salts;
- Hexachloronorbornadiene;
- Hexafluoropropylene oxide; and
- 4,4′-methylenebis(2-chloroaniline) (MBOCA)

The reporting requirements vary from substance to substance. In some instances, EPA will require the manufacturer to submit a PMN form (7710-25). In some cases, the EPA requires site information and estimates of quantities manufactured, imported, or processed over a specified period of time, number of employees exposed, and possibly quantities and methods of disposal.

The reporting deadline varies per chemical substance as well.

PAIR Reporting [Part 712]

40 CFR Part 712 requires manufacturers and importers to provide EPA with information about the production, use, and exposure for specifically listed chemical substances. The information is submitted on a standardized form (EPA Form 771-35). It is a one-time reporting obligation for anyone manufacturing essentially more than 1,100 pounds of the listed chemical substance before the reporting deadline. The report will be based on the most recently completed fiscal year of the manufacturer as of the effective date of the listed substance.

Health & Safety Data [Part 716]

The EPA has a list of several hundred chemical substances in 40 CFR Part 716 for which they require certain manufacturers to submit all unpublished health and safety studies of the listed substance (and mixtures containing the listed substance). The rule has a limited applicability and reporting time. Only manufacturers (including importers) within the North American Industrial Classification System (NAICS) codes 325 or 32441 are required to submit studies. In some instance, the EPA may require reporting from facilities other that the NAICS 325 and 32441 facilities. For example, EPA recently promulgated a rule that requires health and safety data from manufacturers and importers of consumer products for use by children that manufacture or import lead or lead compounds [73 FR 5109, January 29, 2008].

The rule applies to any regulated manufacturer that manufactured the listed chemical within 10 year prior to EPA's listing the substance in Part 716 and those that manufacture or propose to manufacture during the reporting period that follows the initial listing. Under 40 CFR 716.65 the reporting period terminates 60 days after the effective date of the listing of the substance (with some exceptions).

Health and safety study data can include:

- Carcinogenicity
- Mutagenicity
- Teratogenicity

- Behavioral effects
- Dermatoxicity
- Pharmacological effects
- Acute/chronic effects
- Ecological effects
- Workplace exposure

Additional Testing/Studies [Parts 790-799]

Under the rules at 40 CFR Parts 790–799, the EPA may require chemical manufacturers and processors to perform research on the environmental and toxicological properties of a chemical. In these regulations, the EPA:

- Identifies the chemical substances, mixtures, and categories of substances and mixtures for which data are to be developed;
- Specifies who is to do the testing (manufacturers and/or processors of substances or mixtures identified in 40 CFR 799, Subpart B);
- Prescribes required tests and standards;
- Provides deadlines for submission of associated reports and data.

Subpart B of 40 CFR 799 contains a list of specific chemicals to which the data generation requirements apply. Among the chemicals listed are:

- Trichlorobenzenes,
- Diethylene glycol butyl ether,
- Diethylene glycol butyl ether acetate,
- 2-Ethylhexanol,
- Fluoroalkenes,
- Commercial hexane,
- Isopropanol

Substantial Risk Reporting

There is a statutory reporting requirement in TSCA §8(e) requiring any manufacturer, processor, or distributor of a chemical substance who has obtained information that reasonably supports a conclusion that the substance may present a substantial risk to human health or the environment to immediately report such information to EPA. As it is a statutory requirement, there is no regulation specifying the details.

Section 8(e) pertains to all chemical substances and mixtures including, but not limited to, the following:

- Research and development chemicals
- Laboratory reagents
- Low-volume chemicals
- Polymers
- Chemicals that are manufactured solely for export
- Intermediates

- Catalysts
- By-products
- Impurities
- TSCA-covered microorganisms and products therefrom

For the purpose of these rules, *person* includes "any natural person, corporation, firm, company, sole-proprietorship, joint-venture, partnership, association, or any other business entity, any state or political subdivision of a state, any municipality, any interstate body, and any department of agency of the Federal government." [43 FR 11111, March 16, 1978] For business entities, the president, chief executive officer, and any others designated as having reporting authority are responsible for reporting substantial risk information to the EPA.

Persons and business organizations are considered to have *obtained information* once an employee who is capable of appreciating the significance of substantial risk information has knowledge of that information. [43 FR 11111, March 16, 1978]

The EPA considers the effects for which substantial-risk information must be reported to include:

- *Human health effects*—include any instance (or pattern of effects or evidence) of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function.
- *Environmental effects*—include ecologically significant changes in species' relationships (e.g., changes in population behavior, growth, survival that in turn affect other species' behavior, growth, survival).

This is information that reasonably supports the conclusion that a chemical created a substantial risk; however, this information need not establish conclusively that a substantial risk exists. To determine whether information is "substantial risk" information, one should consider the following criteria:

- The seriousness of the adverse effect
- The fact or probability of the effect's occurrence

Substantive risk information must be reported to the EPA unless the person has actual knowledge that the agency has been adequately informed of such information. Reportable information may be obtained through direct control studies (i.e., in vivo and in vitro experiments and tests, epidemiological studies, environmental monitoring) or reports and studies of undesigned uncontrolled circumstances (i.e., medical and health surveys, clinical studies, report concerning and evidence of effects in consumers, workers, or the environment).

The record civil administrative penalty of $10.25 MM involved a company that EPA alleged had information about substantial health risks associated with a synthetic chemical that was used to produce several broad distribution products. The company failed to submit this information to EPA under the TSCA §8(e) standards. The statute not only requires the manufacturer be vigilant in collecting information on the effects of their substances, it mandates communication to the EPA. Whether the hazards are real or significant has no bearing on the reporting requirements. Failure to report can bring significant financial penalties to the manufacturer (or importer).

Records of Allegations of Significant Adverse Reactions

40 CFR Part 717 requires any manufacturer, processor, or distributor of a chemical substance to keep records of records of significant adverse reactions to human health and the environment and to make these records available for inspection by the EPA. According to the rules allegations can come from various sources including employees, customers, neighbors, or other companies and organizations. The EPA defines "significant adverse reactions" as follows:

- Long-lasting or irreversible damage (e.g., cancer or birth defects)
- Partial or complete impairment of bodily functions
- Impairment of normal activities experienced by all or most person exposed at one time
- Impairment of activities that are experienced each time an individual is exposed
- Gradual or sudden change to the composition of animal or plant life in an area
- Abnormal number of deaths of an organism
- Reduction in the reproductive rates of an organism
- Reduction in agricultural activity
- Alterations in behavior or distribution of a species
- Long-lasting or irreversible contamination of the environment

Known effects (e.g., published in MSDSs or on product labeling) and incidents subject to release reporting requirements are not subject to these rules.

The manufacturer must keep these allegation records for at least 30 years if they are related to an employee's health. All other allegation records must be retained for at least five (5) years [40 CFR 717.15].

TSCA and Customs

Under U.S. Customs rules at 19 CFR Part 12, each import shipment of a chemical substance must include one of two certification statements:

"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."

-or-

"I certify that all chemicals in this shipment are not subject to TSCA."

It is the responsibility of the shipper to make this certification. The Customs officers are well trained to look for this certification for any incoming shipments of chemicals. If a shipment is not in compliance with TSCA, it is detained. If not brought into compliance or returned to the country of export by certain deadlines (usually 90 days), the shipment is destroyed. The enforcement

against the client discussed earlier receiving paint from their affiliate in Europe was initiated based on the Customs not finding a TSCA certification with the paperwork for their shipment.

Good Faith Effort to Determine Constituents

The EPA puts the burden on the importer to determine the chemical constituents in their shipments:

"(c) *The section 13 rule*—(1) *General certification*. ***** (iii) EPA expects that this certification will be based upon actual knowledge of the importer in most cases. However, EPA realizes that sometimes importers may not have actual knowledge of the chemical composition of imported mixtures. In these cases, the importer should attempt to discover the chemical constituents of the shipment by contacting another party to the transaction (e.g., his principal or the foreign manufacturer). This person may be able to identify the components of the mixture, or at least state that the substances comply with TSCA. The greater the effort an importer makes to learn the identities of the imported substances and their compliance with TSCA, the smaller his chance of committing a violation by importing a noncomplying shipment. If a shipment is ultimately determined to have violated TSCA, the good faith efforts of the importer to verify compliance, as evidenced by documents contained in his files, may obviate or mitigate the assessment of a civil penalty under section 16 of TSCA." [40 CFR 707.20(c)(1)(iii)]

International Programs

REACH, or "Registration, Evaluation, Authorization and Restriction of Chemicals" was adopted by the European Union on December 18, 2006. The program came into effect on June 1, 2007 and can impact any U.S. company that exports chemical substances (including those in articles) into any of the 27 EU countries. The core of the REACH program is the registration of chemical substances. Registration of new chemicals must occur before import into the EU (similar to the TSCA PMN requirements in the U.S.). REACH also requires registration of substances that have been placed on the EU market or manufactured in the EU at least once in the 15 years prior to June 1, 2007. Registration will apply to any person manufacturing or importing substances into the EU in an annual quantity of 1 ton or greater. However, the deadline is phased in through May 31, 2018 with larger quantities requiring registration as early as 2008.

Although the specific rules are still being developed, the registration can only be done by companies based in the EU, or by a sponsor within the EU. U.S. companies will need to partner with their EU affiliates, locate a sponsor, or pay to become a party to a registration from another manufacturer. This effort will need to be completed prior to the appropriate registration for your substance or article.

Constituents Management

To effectively manage their facility's TSCA and other compliance burdens, the SH&E manager need to implement systems to identify and track every chemical constituent that is either:

- Produced at or within their facility, or
- Brought into their sphere of management control

Such a "knowledge-based constituent management system" can not only eases the manager's concerns of compliance assurance, but may even provide opportunities to reduce costs or compliance burdens. A good constituents management system is predicated upon mass balance accounting. "Mass balance" is defined at Section 11023(l)(4) of Title 42 of the United States Code as:

> "an accumulation of the annual quantities of chemicals transported to a facility, produced at a facility, consumed at a facility, used at a facility, accumulated at a facility, released from a facility, and transported from a facility as a waste or as a commercial product or byproduct or component of a commercial product or byproduct."

Mass balance accounting is not [yet] explicitly required by law, but is offered as a compliance *option* under many regulations. The more you know about chemical flow through your operations, the less you will be required to analyze waste products and environmental releases to document compliance. Usually, obtaining and maintaining knowledge through mass balance accounting is far less expensive and more certain than attempting to analyze "unknowns" after the fact.

The first step to developing a mass balance accounting system is to identify the materials being received by the facility (by chemical constituent and weight percent in mixtures). Efforts should be focused first on the most environmentally "significant" constituents (i.e., those most likely to be regulated or to cause environmental harm). The five steps to identifying constituents in product mixtures are:

1. Ask the vendor
2. Offer confidentiality
3. Use a different vendor/product
4. Threaten to analyze and publish results
5. TAKE ALL RISK

The next stage in assuring the accuracy of a mass balance accounting system is to assure that "unknown" chemicals do not enter your facility. Remember, a small amount of a hazardous constituent can cause considerable compliance headaches! Consider all potential chemical routes of entry into the facility, including:

- Purchase orders,
- Standing and blanket orders (products may change over time),
- On-site contractors,
- Maintenance contracts,
- Sales samples,
- Petty cash purchases,
- Water supply, and
- Within equipment (mercury switches, lead acid batteries, hearing aid batteries, electronic circuit boards).

Tracking Constituents Through the Facility

As your mass balance accounting system develops, you will also want to begin tracking actual chemical flows through your facility. Again, controlling the point of entry for chemicals coming into your facility is key to assuring the effectiveness and accuracy of your efforts. Your point of entry procedures will need to include provisions for logging chemicals into the chemicals tracking system, tagging the containment devices, and training personnel so that constituents may begin to be tracked through the facility.

Comprehensive Facility Modeling

The raw knowledge collected up to this point will be valuable in itself for evaluating environmental and regulatory issues as they arise. However, to be most useful and proactive, you will want to incorporate this information into a facility-wide mass balance model. This model will track chemical constituents through facility processes and will identify chemical changes and vectors from each operation. Initially, developing a model that represents every chemical change, transfer, or release at your facility may appear inordinately complex and difficult. It can, however, be simplified by breaking your overall operation into discrete units, each of which can be examined independently. Typical "units of operation" might consist of:

- Individual machines (e.g., the wave solder machine that uses its own specific materials or the Freon degreaser in the pre-assembly room);
- Groups of machines performing the same or similar functions (e.g., all carbon-steel grinders or all ammonia-based blue-line printers);
- Departments performing a relatively uniform and specific function (e.g., the printing department);
- A sub-facility or building (e.g., the wastewater treatment plant or the chemical storage warehouse)

The simplest and most useful method for modeling each unit of operation is the steady-state model. This model considers the operation essentially to be a black box; then examines the units of input and output for each cycle of operation. The cycle of operation can be chosen at random (one work shift, one month, one batch, etc.), provided that each input and output can be quantified for that cycle. For each constituent involved in the operation over the chosen cycle, the following equation should be true:

$$(I+C)–D=O$$

I - The total quantity of that chemical constituent input to the process in all material inputs
C - The quantity of that chemical constituent created in the process
D - The quantity of that chemical constituent destroyed in the process
O - The total quantity of that chemical constituent output from that process (including product, waste, and environmental releases)

Once individual unit operation models are complete, these may be linked into a comprehensive picture of facility operations. This is accomplished simply by linking the outputs of one unit of operation to the inputs of another. For example, among other outputs, a machining operation generates oily metal parts with a few metal fines adhering to them. These parts are transferred to a degreaser. In your unit of operation model for the machining operation, these are represented as a

collection of constituents, including metal, oil, oil additives, and perhaps some dirt. One input for your degreasing unit of operation (oily parts to be cleaned) should be identical in chemical constituents and percent concentrations to the oily parts output from machining. Linking all unit operations together will yield a material flow chart, through which different constituents take different paths.

The final and on-going step in mass balance accounting is to test and continually refine your assumptions, your data, and your model itself. In addition, you may wish to develop and maintain your own QA/QC systems for the purpose of assuring the chemical composition of wastes and releases. There are three specific types of systems you might consider:

Operations Auditing: Periodic audits of operations can help to assure that processes and materials used have not changed. They may also help to identify chemicals, releases, or other issues not included in your models. This is particularly true where outside (consulting or corporate) assistance is used in the audit. An operations audit may be as informal as making periodic "rounds" of the facility or may be as structured as a formal week-long study. To minimize redundancy, audits of your mass balance accounting system and constituent information should be integrated with related environmental compliance audits.

QC Sampling and Analysis: Although sampling and analysis *alone* is an expensive and often unreliable means of assuring environmental compliance, it can be used effectively as a means to test and control the quality of your "knowledge." This sampling and analysis is different from that used to identify wastes and releases in two ways. First, it is less frequent, since it need not offer statistical confidence. Second, analyses are often done by less complex and less expensive "screening" methods (total organic halogen test kits, simple meters, indicator papers, GC screens, etc.) since you are looking primarily for anomalies, not data.

Chemical Tracking: Simple systems of inventory recordkeeping and bar coding can be used to track exactly where in a facility any particular chemical constituent is at any given time. To achieve this tracking, specific receiving controls must be in place.

First, such a system assumes all significant chemical constituents of each material you use are known. When received at your facility, the receiving clerk enters the material ID (your own internal name or code number), the number of containers, and the quantity per container. The computer automatically prints out one bar-coded label for each container. At the same time, the computer registers the material as present in the receiving department. In the computer, each bar code is now associated with a collection of chemical constituents and the quantity of each.

When a material is moved from one operations area to another, the movement is registered in the computer. This is done either by scanning the material with a dedicated bar code reader/terminal at the receiving location or by scanning the material's bar code followed by another bar code indicating the area to which the material is going. (You need not tell the computer where the material is coming from. It already knows.)

One client of ours developed a comprehensive tracking system similar to this discussion. On occasion they would randomly track a container through their facility to measure the effectiveness of the mass-balance accounting system. It was not uncommon for them to have a success rate of 95 percent! Although there still could be concerns with the missing five percent,

How many facilities without a comprehensive constituents management could say they know where all their constituents are with a 95% level of confidence.

Conclusion

Although there are significant cost and time commitments in developing a constituents management system, the cost of losing control of your chemical substances can be even greater. The requirements under the Toxic Substances Control Act are dependant on the manufacturer, importer, processor, and user to know their chemical substances. Since TSCA is the program that provides EPA with the most significant information about chemical substance before manufacture and distribution, rules that are simply paperwork requirements still carry a heavy hammer should the paperwork be wrong or missing. The challenges are increasing as economies see no boundaries. The European Unions' REACH program is the next step in demanding that facilities know and have complete control of all of their constituents. Those facilities that prepare now will actually be at a business advantage compared to those that delay.

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