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TSCA, SNURS AND CONSENT ORDERS AND YOUR SDS

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TSCA, SNURS AND CONSENT ORDERS

1. The Road to the Reformed Toxic Substances Control Act (TSCA)
2. Significant New Use Rules (SNUR)
3. Consent Orders (CO)
4. Could (Should) this change?

THE TOXIC SUBSTANCES CONTROL ACT (TSCA) – WHERE WE'VE BEEN…

Why did we need TSCA in 1976?

- In a 1971 report, the Council on Environmental Quality (CEQ) urged the Federal government to regulate toxic substances because the existing law only took effect after the damages were done and did nothing to prevent future damage.

By the numbers

- TSCA grandfathered ~62,000 substances
- 1976 - 2018, EPA has inventoried ~22,000 substances
- EPA required only 200 to be tested

How EPA obtained more information?

- Mutual agreement with the chemical company
- Voluntary industry efforts under the HPV Challenge Program or through the Sustainable Futures (SF) Initiative model, which allows companies to voluntarily screen their products that might pose risks to human health or the environment.

THE TOXIC SUBSTANCES CONTROL ACT (TSCA) – WHERE WE ARE…

How did the Frank. R. Lautenberg Chemical Safety for the 21st Century Act change the law?

More effective federal oversight of chemicals will:

- Give Americans greater confidence that chemicals in commerce are being used safely
- Reduce the number of inconsistent state-based chemical initiatives that impede interstate commerce and send mixed messages to consumers.

The Safety Principle

Centralizing concept (Safety Principle) is unreasonable risk, the evaluation of which:

- Does not include consideration of cost/benefit factors
- Focuses on conditions of use (COU) as determined by the U.S. Environmental Protection Agency (EPA)
- Includes consideration of potentially exposed or susceptible subpopulations (PESS) identified as relevant by EPA

Key Changes:

- EPA to evaluate existing chemicals, with clear and enforceable deadlines
- EPA will now be able to collect up to $25 million a year in user fees from chemical manufacturers and processers, supplemented by Congressional budgeting
- Increased public transparency for chemical information

THE TOXIC SUBSTANCES CONTROL ACT (TSCA) – WHERE WE ARE…

Key Provisions:

Existing Chemicals

Chemical Assessments

- Prioritization
- Risk Evaluations
- Risk-Based Safety Standard
- Action to address unreasonable risks
- Manufacturer-requested assessments

Chemical Testing Authority

New Chemicals

Pre-Market Review of New Chemicals - affirmative action needed

Confidential Business Information – substantiation – will automatically expire

Source of Sustained Funding

Preservation of State Laws

Preemption of State Laws

Exemptions

THE TOXIC SUBSTANCES CONTROL ACT (TSCA)- WHERE WE ARE GOING…

What Do I Need to Do Differently Under TSCA?

Centralizing concept is unreasonable risk – does not include cost/benefit analysis focuses on Conditions of Use (COU) and Potentially Exposed or Susceptible Sub-populations (PESS)

Section 5 Manufacturing and Processing Notices for Non-Conformance / Significant New Use (NC/SNUs)

~~Probably~~ more Significant New Use Rule (SNURs)

Three alternatives in 5(a)(3)

- **Issue a NC/SNU because it presents an unreasonable risk – REQUIRED to regulate**
- **Don't Know – could present and unreasonable risk to PESS – REQUIRED to regulate**
- **OK – not likely to present an unreasonable risk – MUST EXPLAIN why**

02

SIGNIFICANT NEW USE RULES

SIGNIFICANT NEW USE RULES (SNURS) –WHAT ARE THEY?

TSCA section 5(a)(3)(C)

Not likely to present an unreasonable risk Determinations

Where the EPA determines that a new chemical or significant new use is *not likely to present an unreasonable risk of injury to health or the environment*,

- without consideration of costs or other non-risk factors,
- including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use,
- EPA will notify the submitter and publish its findings

SIGNIFICANT NEW USE RULES (SNURS) –WHAT ARE THEY?

SNURs for Existing Chemicals (i.e., SNURs not promulgated as a result of TSCA New Chemicals Program review)

- TSCA Section 5(a) Significant New Use Rules (SNURs) can be used to require notice to EPA before chemical substances and mixtures are used in new ways that might create concerns.

EPA can determine that a use of a chemical substance is a “significant new use” by rule after considering all relevant factors, including:

- Projected volume of manufacturing, processing distribution, and disposal
- Extent to which a use changes the type or form of exposure of humans or the environment
- Extent to which a use increases the magnitude and duration of exposure of humans or the environment
- The hazard communication associated with the use

SIGNIFICANT NEW USE RULES (SNURS) –WHAT ARE THEY?

SNURs for Existing Chemicals (i.e., SNURs not promulgated as a result of TSCA New Chemicals Program review)

Once EPA determines that a use of a chemical substance is a significant new use,

- TSCA requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import), or process the chemical substance for that use.

EPA to

- assess risks that may be associated with the significant new use, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use;
- make a determination under the statute; and, if appropriate,
- regulate the proposed activity before it occurs.

SIGNIFICANT NEW USE RULES (SNURS) –WHAT ARE THEY?

SNURs for New Chemicals (i.e., SNURs promulgated as a result of TSCA New Chemicals Program review)

- EPA can issue SNURs for new chemicals following the Agency's review or during the review period. Because there is detailed communication between EPA and PMN/MCAN/SNUN submitters during the review period, the EPA generally issues these SNURs as "direct final" rules.

SNURs not associated with Orders.

- A SNUR can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns,
- The ability to issue a SNUR during or after the review period can enable EPA to focus its technical analysis on the intended conditions of use of a chemical and defer further analysis of reasonably foreseen conditions of use until such time as the submitter (or any other entity) actually intends to undertake them.

SIGNIFICANT NEW USE RULE (SNURS) –WHAT ARE THEY?

Is My Chemical Subject to a SNUR?

- Substances on the TSCA Inventory, subject to a SNUR, are designated as such by an "S" flag in the Inventory listing.
- Information on non-confidential chemical substances can be found in the TSCA Chemical Substance Inventory.
- EPA maintains a CBI version of the TSCA Inventory. If an intended manufacturer submits a PMN or a Notice of Bona Fide Intent to Manufacture on a substance that has a listing on the Confidential Inventory, the Agency will notify the submitter of the existence of the SNUR.
- It is always the ***obligation of the manufacturer or processor*** selling a chemical substance to notify the user of the SNUR status of that substance. Buyers of a chemical substance whose identity is confidential, and thus not disclosed to them, should seek certification from the sellers that their intended use is not a significant new use.

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CONSENT ORDERS

CONSENT ORDERS – WHAT ARE THEY

TSCA section 5 (e) Orders

One outcome of EPA's review may be the issuance of an order. Most are Consent Orders that are negotiated with the submitter of the notification.

The Agency can determine that:

- the information is insufficient to make a reasoned evaluation of the health and environmental effects of the new chemical substance or the significant new use,
- or the manufacture, processing, distribution in commerce, use or disposal of the chemical may present an unreasonable risk to health or the environment,
- without consideration of costs or other non-risk factors,
- including an unreasonable risk to a potentially exposed subpopulation identified as relevant to the Administrator under the conditions of use, or
- the chemical substance is or will be produced in substantial quantities and will either enter the environment in substantial quantities or there may be significant or substantial human exposure to the substance.

CONSENT ORDERS – WHAT ARE THEY

TSCA section 5 (e) Orders

Where EPA makes one of these determinations, EPA must issue an order under TSCA section 5(e). These orders are typically issued on consent.

A section 5(e) order typically contains some or all of the following requirements as conditions:

- Testing for toxicity or environmental fate once a certain production volume or time period is reached
- Use of worker personal protective equipment
- New Chemical Exposure Limits (NCELs) for worker protection
- Hazard communication language
- Distribution and use restrictions
- Restrictions on releases to water, air and/or land, and
- Recordkeeping.

A company subject to an Order that requires testing must notify the EPA Monitoring of certain study-related information within 10 days of scheduling any study required to be performed pursuant to the Order

CONSENT ORDERS – WHAT ARE THEY

SNURs following Orders

TSCA section 5(e) or 5(f) Orders are only binding on the original PMN submitter for that substance.

- Generally, after issuing a section 5 Order,
  - EPA generally promulgates a SNUR that requires notice to EPA by any manufacturer or processor who wishes to manufacture or process the chemical in a way other than described in the terms and conditions contained in the Order.
  - TSCA section 5(f)(4) requires EPA to either initiate a SNUR rulemaking or explain its reasons for not doing so following action under section 5(e) or 5(f).
  - These new use designations are typically those activities prohibited by the Section 5 Order.

COULD (SHOULD) THIS CHANGE?

It can be more efficient for EPA to address concerns associated with reasonably foreseen conditions of use by issuing a SNUR that applies to all parties, including the submitter, rather than by issuing an order to the submitter addressing activities the submitter does not intend to undertake, and then taking an additional regulatory action to issue a SNUR.

- EPA on SNURs-Public Meeting December 2017: Where the EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions …the EPA will assess whether those concerns can be addressed through SNURs.
- EPA's expectation is that SNURs will be
  - effective in addressing concerns for which the EPA previously issued consent orders (CO) and
  - will still be protective but will be more efficient.

COULD (SHOULD) THIS CHANGE?

EPA's efforts to coordinate its SNUR program with Canada

- EPA and Environment and Climate Change Canada/Health Canada (ECCC/HC) have been working together under the Regulatory Cooperation Council (RCC) to conduct a comparison of the new chemicals review programs in both nations, specifically EPA's SNUR and Canada's Significant New Activity (SNAc) programs
  - that require notice to the governments before chemical substances and mixtures are used in new ways that might create environmental or health concerns.
  - EPA and Canada convened stakeholders throughout the supply chain and facilitated two roundtable discussions to identify opportunities for regulators and stakeholders to increase regulatory transparency and coordination between the two countries.

TSCA, SNUR, CO
YOUR TO DO LIST

Be aware that SNURS are the new normal!

Or are they??

- Know the analogues that EPA may look at
- Strategize how to discuss with your downstream user – how to add to your Technical Data Sheets or SDS
- EPA does have the authority to require tests even without a CO
- Suppliers are obligated to tell you of a SNUR – sometimes information gets lost so (mergers, acquisitions, divestures) – So ASK

SDS AND SNURS

SDS

United States Department of Labor

Occupational Safety and Health Administration – OSHA

Hazard Communication Safety Data Sheets

The Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide Safety Data Sheets (SDSs) (formerly known as Material Safety Data Sheets or MSDSs) to communicate the hazards of hazardous chemical products. As of June 1, 2015, the HCS will require new SDSs to be in a uniform format, and include the section numbers, the headings, and associated information under the headings below:

Section 1, Identification

Section 2, Hazard(s) identification

Section 3, Composition/information on ingredients

Section 4, First-aid measures

Section 5, Fire-fighting measures

Section 6, Accidental release measures

Section 7, Handling and storage

Section 8, Exposure controls/personal protection

Section 9, Physical and chemical properties

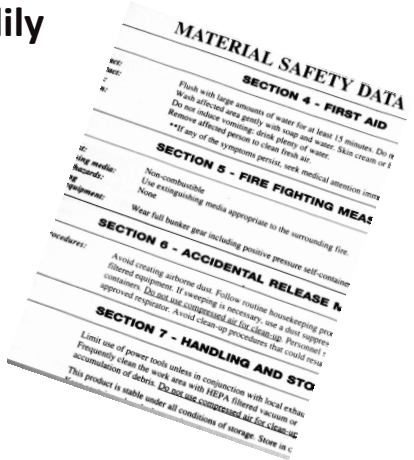
Section 10, Stability and reactivity

Section 11, Toxicological information

Section 12, Ecological information*
Section 13, Disposal considerations*
Section 14, Transport information*
Section 15, Regulatory information*
Section 16, Other information, includes the date of preparation or last revision.

Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15 (29 CFR 1910.1200(g)(2)).

Employers must ensure that SDSs are readily accessible to employees.


MATERIAL SAFETY DATA

SECTION 4 - FIRST AID

SECTION 5 - FIRE FIGHTING MEAS

SECTION 6 - ACCIDENTAL RELEASE M

SECTION 7 - HANDLING AND STO

SDS

Changes due to the Inventory Reset

- Users of Safety Data Sheets (SDS) often rely on the regulatory information of Section 15 to determine the compliance status of a chemical substance, and ultimately the product containing that substance;
- Substances not listed on the EPA TSCA Inventory cannot be placed on the market, whether through manufacturing, importation or processing/formulating— unless exempted by TSCA.
- Although OSHA makes the information in Section 15 optional, it has become standard practice to include “inventory” status in this section.
- It will likely no longer suffice to simply state “US TSCA Inventory – listed” in Section 15 of the SDS. Instead, manufacturers, importers, etc., will now likely need to differentiate between whether a substance is on the “active” or “inactive” inventory,

SDS

Changes due to PMN Risk Assessment

You have a OSHA compliant SDS

You submit the PMN

During either the engineer/hazard review or the focus/risk review

- The EPA asks for changes in certain sections usually 7, 8, 13, (14)

Example 1 Human Health – dermal exposure Section 8 and any place else you use gloves and PPE

- The EPA had some concerns - requested that the SDS be changed to state “impervious” gloves as PPE
- Remedy state impervious gloves in SDS

SDS

- **Changes due to PMN Risk Assessment**
- Example 2 Calculation of Concentration of Concern
- E-Fast Model -The Exposure and Fate Assessment Screening Tool provides estimates of the concentrations of chemicals released to air, surface water, landfills, and consumer products. Estimates provided are potential inhalation, dermal and ingestion dose rates resulting from releases of chemicals.
  - Modeled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in an exposure assessment in the absence of or with reliable monitoring data.
- The concentration of concern, CoC, (sometimes reported in parts per million, parts per billion, or parts per trillion) provides the concentration of a given chemical in a stream. This measure is determined by dividing the lowest chronic toxicity value by a factor of 10. Harm to the aquatic environment is more likely to occur if the CoC is exceeded.
- Issue a SNUR, one part is to reference CoC in Sect 13 and 14

SDS

What to Do

- Automated - overrides special language
- Be specific: collect all rinse water, use licensed waste handler for…
- Have discussion understand what triggers “words” and program them
- Be consistent if not hazardous but need extra warning for EPA use the non-regulated areas

SDS

What to Do

- Can use the caution to comply with local regulations as they may differ
- The SDS is a mode of communication to the down stream user.
- You may not control the actions of the down stream user but you can adequately warn them via the SDS. This is a concern of the EPA (cradle to grave).
- Can use Technical Data Sheet or Specification Sheet, but an SDS must be updated when new information is obtained, so the EPA considers the SDS as the best method for communication.
- Need communication between DOT, OSHA and EPA.

KEEP CALM BUT TAKE ACTION

HOW WE AT INTERTEK CAN HELP

- **Regulatory Review**: Analyzing product lines for compliance under global regulations
- **Modeling**: run model to anticipate possible questions
- **Preparation**: Developing notification dossiers under global regulations
- **Science**: Providing technical input into the dossier preparation and assessment process
- **Confidential Business Information**: Developing confidentiality substantiation and compliant generic names
- **Interpretation**: Determining your obligations to respond to mandatory and voluntary chemical inquiries
- **Documentation:** Preparing mandatory and voluntary responses to government initiatives
- **Surveillance:** Tracking draft and final risk assessment notices and proposed risk management measures
- **Smart Planning**: Providing strategic advice regarding impact of proposed risk management measures
- **Consultation**: Working with the regulatory authorities on matters relating to any proposed hazard-assessment outcomes and risk management measures for your chemicals

Analysis of key details:

Sales channel	Supply chain
Finished products (articles), chemical substances and mixtures	Determination of certification requirements
Determination of reporting requirements	Development of notification/reporting strategies
Development of confidentiality claim substantiation language	Determination of timelines

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REMINDER -YES YOU CAN VIEW THEM ON YOUR MOBILE

For general Information on TSCA and on LCSA, and a preliminary to do list, please see my first webinar at

- http://www.intertek.com/knowledge-education/toxics-substance-control-act-webinar/

For information on CBI and some practical and maybe not so intuitive reminders, please see my second webinar at

- http://www.intertek.com/knowledge-education/tsca-lcsa-webinar/

For an overview after one year and what companies should be thing about, please see my third webinar at

- http://www.intertek.com/knowledge-education/tsca-lcsa-interim-report-webinar/

For a discussion on the Framework Rules, please see my fourth webinar

- http://www.intertek.com/knowledge-education/us-tsca-framework-rules-webinar/

For a look back at 2017 and forward to 2018

- http://intertek-cdn.s3.amazonaws.com/mail/images/WebinarRecording/Intertek-Webinar-TSCA-A-Brief-Look-Back-and-Things-to-Look-Forward-to-in-2018-March2018.pdf