

Metalworking Fluids Committee Meeting

April 12, 2024 | 10:45 am – 12:15 pm PT
Loews Coronado Bay Resort
Coronado, California

Jeffery L. Leiter, General Counsel

Benjamin Idzik, Regulatory Counsel

Bassman, Mitchell, Alfano & Leiter, Chtd.

John K. Howell, Ph.D., **GHS Resources, Inc.**

John Burke, CMFS FSTLE, **Quaker Houghton Chemical, Corp.**

Emerging Issues

Chemical Data Reporting

- Broadly, Section 8(a) of the Toxic Substances Control Act (TSCA) requires certain manufacturers and importers to submit detailed reports on certain chemical substances that they manufacture or import.
- Who must report?
 - All parties that have manufactured / imported more than 25,000 pounds or more of a chemical that are listed on the TSCA Inventory that they have manufactured / imported during a four-year reporting period.
 - Reduced threshold of 2,500 pounds for certain chemicals that are listed under TSCA's Substance Registry Services (SRS).
- What is the current reporting period?
 - 2020 – 2023
- Reporting required for all four years if threshold is met in any year of the CDR cycle.

Chemical Data Reporting

- What must be reported?
 - For each year during the reporting period:
 - Chemical name
 - Production volume
 - For principal year during the reporting period:
 - Additional details such as (1) company & site information at each manufacturing / import site, (2) industrial processing & use, (3) chemical identification, (4) information relating to the manufacturing, (5) consumer & commercial uses for each chemicals.
- Reporting standard: “known to or reasonably ascertainable by” for all data.

Chemical Data Reporting

- Small Manufacturer / Importer Exemption
 - (1) less than \$12 million in sales in 2023, or
 - (2) companies that manufactured or imported less than 100,000 pounds of a subject chemical in 2023 and also had less than \$120 million in sales that same year.
- Exemptions
 - Non-TSCA chemicals
 - Non-isolated intermediates

Chemical Data Reporting

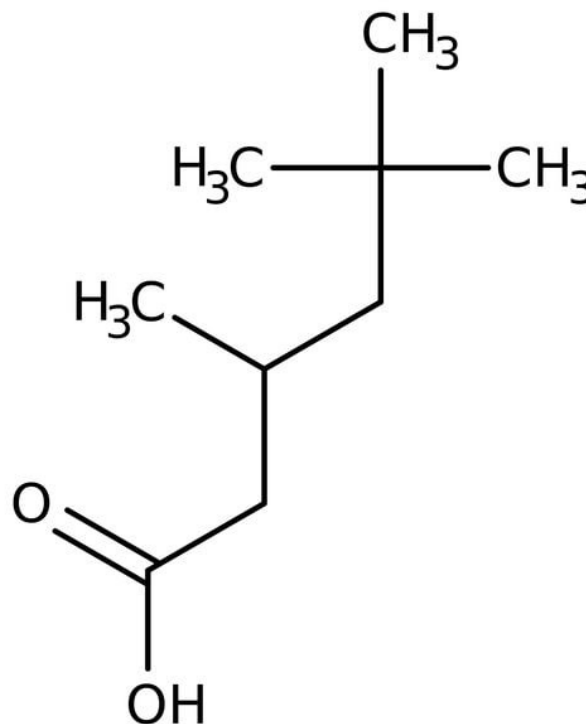
- Takeaways for ILMA Members
 - All CDR reporting must be filed electronically (through e-CDRweb reporting tool and EPA's Central Data Exchange (CDX) system).
 - Submission period: June 1, 2024 – September 30, 2024
 - Time consuming & complicated process, don't delay!
 - Ensure your company's access to the e-CDRweb reporting tool and the CDX system.

Repro Tox 1B – Iso-, Neodecanoic Acids

The issue: ECHA looking at some branched chain organic acids for their ability to cause reproductive harm; two acids formulated in combination with alkanolamines to add rust preventive properties in MWFs, **isononanoic acid** and **neodecanoic acid**, are included in the group being studied.

Repro Tox 1B – Iso-, Neodecanoic Acids

- Isononanoic acid
- 3,5,5-trimethyl hexanoic acid
- EC# 221-975-0
- CAS# 3302-10-2



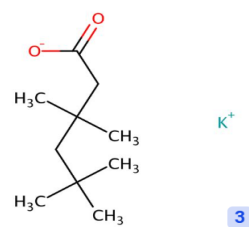
Repro Tox 1B – Iso-, Neodecanoic Acids

- Neodecanoic acid
- EC# 248-093-9
- CAS# 26896-20-8

• CAS Number: 26896-20-8 [1](#) [2](#).

Components of this mixture include acids with the common property of a “trialkyl acetic acid,” having three alkyl groups at carbon two. Some specific components are:

1. 2,2,3,5-Tetramethylhexanoic acid
2. 2,4-Dimethyl-2-isopropylpentanoic acid
3. 2,5-Dimethyl-2-ethylhexanoic acid
4. 2,2-Dimethyloctanoic acid
5. 2,2-Diethylhexanoic acid [2](#).



Repro Tox 1B – Iso-, Neodecanoic Acids

Based on currently available information, there is a need for (further) EU regulatory risk management – Restriction for reproductive toxicity hazards due to the potential for release/ exposure from industrial, professional, consumer and article uses of **2-ethylhexanoic acid (EC 205-743-6) and its salts** (Subgroup 5), **3,5,5-trimethylhexanoic acid (EC 221-975-0) and its salts** (EC 220-169-6, 258-901-1, 264-731-9, 283-563-7, 299-890-3 and EC 258-901-1⁷), and **EC 200-922-5⁸, 248-093-9, 248-570-1, 246-885-9, 201-195-7, 250-178-0, 261-716-9, 266-369-7, 285-549-6, 421-140-2, 700-021-1, 812-724-1 and 940-217-6** (plus 12 UVCB salts that read-across to them: **247-978-7, 248-370-4, 248-374-6, 248-375-1, 257-446-6, 260-742-8, 282-780-4, 270-064-4, 270-296-6, 271-378-4, 295-362-1 and 295-363-7**).

2-ethylhexanoic acid (EC 205-743-6) and its salts

2-ethylhexanoic acid (EC 205-743-6) and its salts are subject to a group harmonised classification which has been published in CLP Annex VI via the 18th

Repro Tox 1B – Iso-, Neodecanoic Acids

3,5,5-trimethylhexanoic acid (EC 221-975-0) and its salts

Compliance check is ongoing for EC 221-975-0 but results from the requested extended one generation toxicity study (EOGRTS) indicate the substance may warrant a Reprotoxic 1B H360FD classification. Once completed, a group harmonised classification is proposed for the substance and its salts. All the substances indicate industrial and professional uses in their registrations, with EC 264-731-9 additional having consumer uses (as a coating) and EC 264-731-9 and 283-563-7 indicating article service life.

Remaining substances with reproductive toxicity hazards with the potential for release/exposure from industrial, professional, consumer and article uses of the substances.

There is an ongoing compliance check for 3 of the substances (2 short-chain acids EC 200-922-5, 248-570-1, and one long-chain acid EC 248-093-9) where various

Repro Tox 1B – Iso-, Neodecanoic Acids



Establishing confidence in new approach methodologies (NAMs): Use of NAMs to refine and strengthen SAR read-across for branched-alkyl carboxylic acids

Corie Ellison, PhD
Procter & Gamble
February 21, 2024



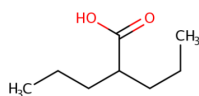
Central Product Safety
Ensuring Safe Products

[EPIC-Webinar-3_Ellison.pdf \(thepsci.eu\)](#)

Repro Tox 1B – Iso-, Neodecanoic Acids

Case Study Problem Statement

Valproic acid (VPA)

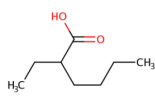


Widely used pharmaceutical

A human teratogen, causing spina bifida in about 1% of babies exposed prenatally

Causes neural tube defects and other abnormalities in animal models

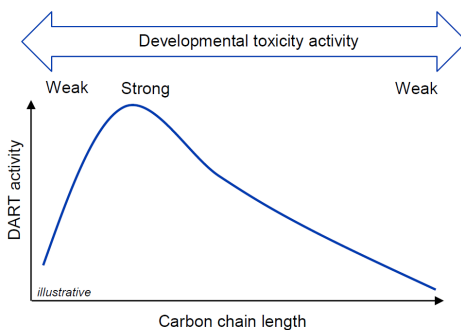
Activity trend for other branched carboxylic acids



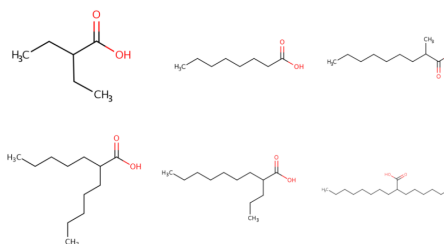
2-Ethylhexanoic acid (EHA)

Isomer of VPA

Developmentally toxic in rodent models



Additional branched carboxylic acids



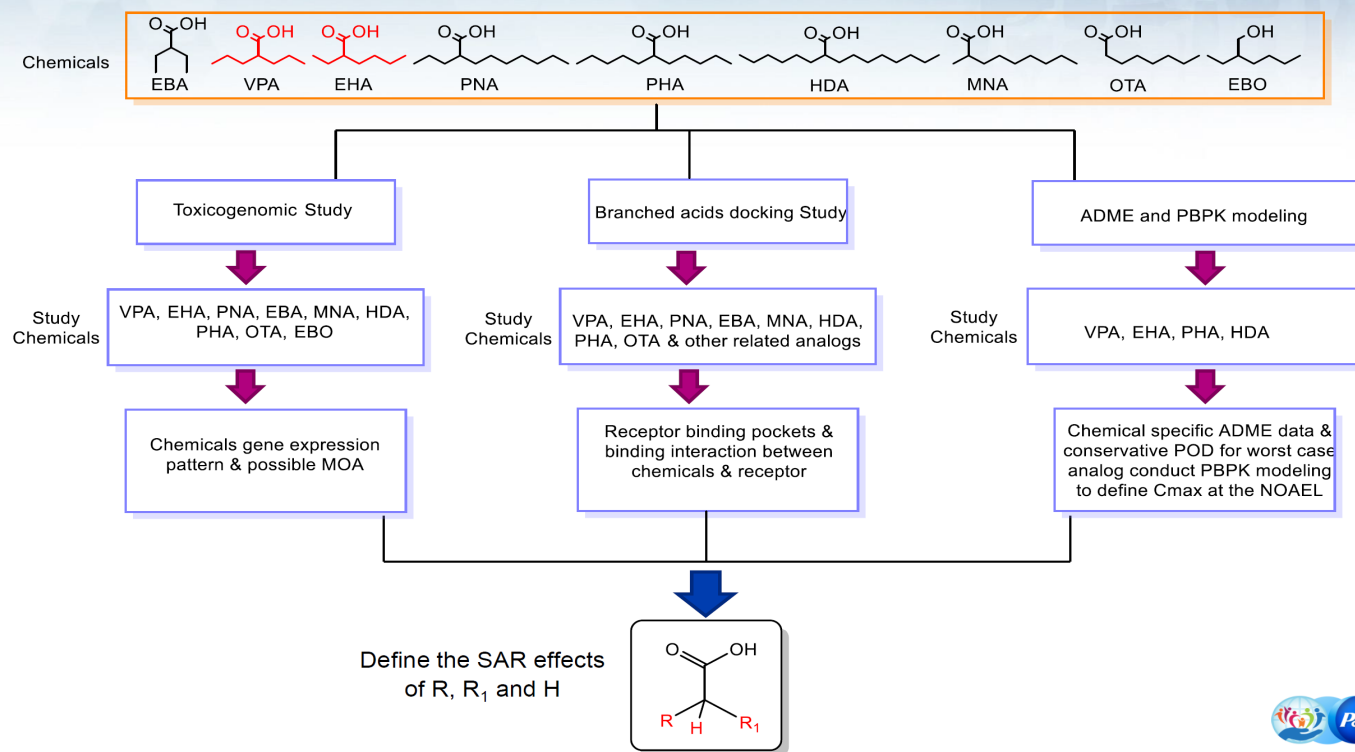
Used in the production of surfactants, lubricants, plastics and other products

Much less data on the developmental toxicity potential

Do they have the potential to have VPA-like effects on development?

Repro Tox 1B – Iso-, Neodecanoic Acids

NAMs Used to Support/Refine Toxicological SAR Read Across



Repro Tox 1B – Iso-, Neodecanoic Acids

MOA of HDAC Inhibitors to Cause Teratogenic Potential

- Many HDAC inhibitors can induce specific malformations in rodents
- Common MoA is histone hyperacetylation and the consequent alteration of gene expression pattern.

HDAC knockout mouse phenotype related teratogenic activity

Class I HDAC1 HDAC3	Class I HDAC2 HDAC3	Class II HDAC	Class I HDAC1
Embryolethal at very early stages of development, probably due to cell proliferation and general growth arrest	Postnatal lethality respectively due to cardiac or skeletal defects	Lethality or altered phenotype in growth response of specific tissues (cartilage and heart muscle)	Knockdown or mutant zebrafish embryos are characterized by developmental defects at the level of the heart, neuroepithelial derivatives, craniofacial cartilages and pectoral fins

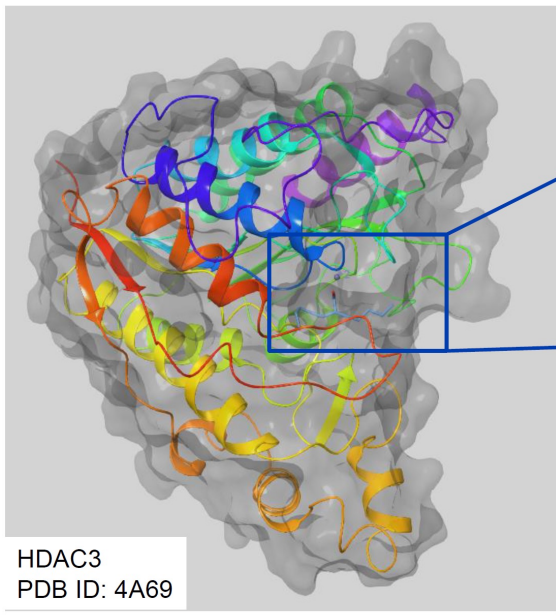


Can we support the transcriptomic results with molecular docking information?

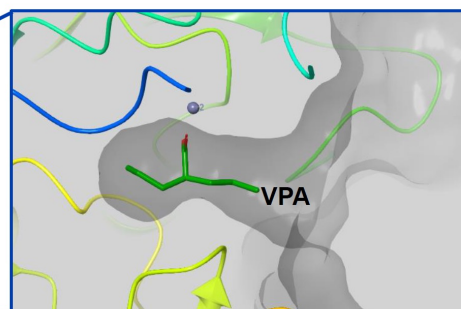
Repro Tox 1B – Iso-, Neodecanoic Acids

Molecular Docking with Histone Deacetylase

Structure of histone deacetylase 3 (HDAC3)



Close up view of HDAC3 binding pocket



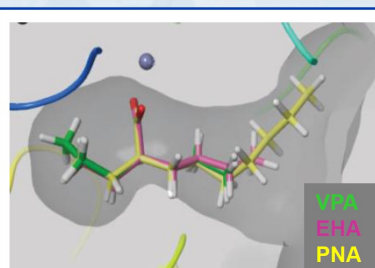
HDAC receptor contains two asymmetric binding pockets:

- (1) small pocket which only fits a shorter alkyl chain
- (2) larger pocket which can tolerate longer alkyl chains

VPA is a good ligand for HDAC3

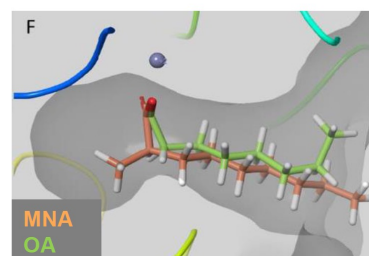
Repro Tox 1B – Iso-, Neodecanoic Acids

Molecular Docking Results



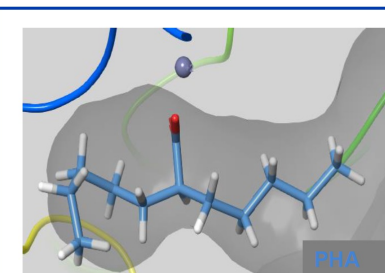
VPA, EHA, PNA

Good fit into HDAC binding pocket



MNA, OA, EBA

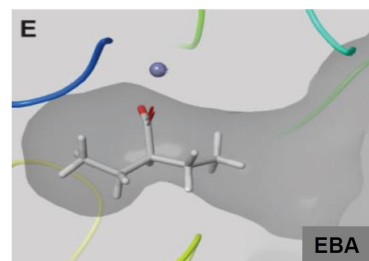
Poor fit into HDAC binding pocket



PHA, HDA

Poor fit into HDAC binding pocket

Too bulky



At least one R group too small

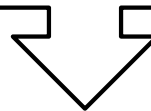
Similar results obtained for HDAC1, HDAC2 and HDAC3

Repro Tox 1B – Iso-, Neodecanoic Acids

- Stay tuned for updates!
- Next UEIL HSE Meeting, 2 May, 2024, Brussels, 10:00 AM GMT +2
- Discussion - Questions

PFAS & Metalworking Fluids

EPA's "PFAS Strategic Roadmap," released in 2021, set out the Biden Administration's commitment to combat PFAS.



**TSCA Section
8(a)(7) PFAS
Reporting**

**Final Rule
Changing TRI
Reporting
Requirements for
PFAS**

**Proposed Rule
Listing PFOS &
PFOS as CERCLA
Hazardous
Substances**

**Proposed Rule
Listing Nine PFAS
as RCRA
Hazardous
Constituents**

PFAS & Metalworking Fluids

TSCA Section 8(a)(7) PFAS Reporting

- EPA published final rule on October 11, 2023.
- Applies to
 - “PFAS”
 - $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons
 - $R-CF_2OCF_2-R'$, where R and R' can either be F, O, or saturated carbons
 - $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons
 - Includes
 - All PFAS listed as active on the February 2023 TSCA Inventory
 - All PFAS with TSCA Section 5 (New Chemicals) Low-Volume Exemptions (LVE) claims
 - May include some fluoropolymers.

TSCA Section 8(a)(7) PFAS Reporting

TSCA Section 8(a)(7) PFAS Reporting

- What must be reported?
 - Chemical or mixture identity, trade name, and molecular structure.
 - Categories of use.
 - Quantity manufactured or processed for each category of use.
 - Descriptions of byproducts resulting from the manufacture, processing, use, or disposal.
 - Existing environmental and health effects information.
 - Number of workers exposed and duration of exposure.
 - Manner or method of disposal and any change in manner or method.
- Some of these data points must already be reported under the Chemical Data Reporting Rule, the Toxics Release Inventory, and Greenhouse Gas Reporting Program.
 - EPA permits submitters to indicate in the CDX reporting tool if they have already reported information.
 - However: This rule requires information for each year in which PFAS was manufactured (or imported).
- Confidential business information protections available.

PFAS & Metalworking Fluids

TSCA Section 8(a)(7) PFAS Reporting

- Who must report?
 - Any person who has manufactured (included imported) PFAS – in any amount – at any time since January 1, 2011, is required to report to the extent the information is known or reasonably ascertainable.
 - No testing or monitoring requirement.
- Who is not required to report?
 - Persons who have only processed, distributed in commerce, used, or disposed of PFAS.
- Takeaways for ILMA Members
 - Most Manufacturing Members fall into the processor category.
 - However, some ILMA members may import PFAS substances.

PFAS & Metalworking Fluids

Final Rule Changing TRI Reporting Requirements for PFAS – (EPA-HQ-OPPT-2023-0223)

- Final rule released in October 2023.
- Adds PFAS to the reporting requirements under the Emergency Planning & Community Right-to-Know Act (EPCRA) and Pollution Prevention Act (PPA).
 - Eliminates a previous exemption that excused manufactures from reporting if their PFAS use was less than 100 pounds.
- Effective November 30, 2023, applies for reporting year beginning January 1, 2024.
 - First reports will be due July 1, 2025.
 - EPA will use information to get a better idea of PFAS releases and waste management.

PFAS & Metalworking Fluids

Comprehensive Environmental Response, Compensation & Liability Act (EPA-HQ-OLEM-2019-0341)

- Initially proposed in September 2022.
- Listing Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) as as CERCLA “hazardous substances.”
 - Any entity handling the material liable for the recovery and remediation costs of releases or threatened releases.
 - Liability extends to current and former owners and operators of facilities where the material was released or disposed as well as generators, arrangers, and transporters.
 - Major financial ramifications.
- After a series of delays, the rule has been sent to the White House Office of Management & Budget (OMB) and is expected to be finalized in March 2024

PFAS & Metalworking Fluids

Resource Conservation & Recovery Act - (EPA-HQ-OLEM-2023-0278)

- Proposed rule released in January 2024.
- Listing nine PFAS as “hazardous constituents” under RCRA.
 - Perfluorooctanoic acid (PFOA)
 - Perfluorooctanesulfonic acid (PFOS)
 - Perfluorobutanesulfonic acid (PFBS)
 - Hexafluoropropylene oxide-dimer acid (HFPO–DA or GenX)
 - Perfluorononanoic acid (PFNA)
 - Perfluorohexanesulfonic acid (PFHxS)
 - Perfluorodecanoic acid (PFDA)
 - Perfluorohexanoic acid (PFHxA)
 - Perfluorobutanoic acid (PFBA)

PFAS & Metalworking Fluids

Resource Conservation & Recovery Act (RCRA) - (EPA-HQ-OLEM-2023-0278)

- Listing nine PFAS as “hazardous constituents” is a preliminary step toward classifying it as a hazardous waste.
- To classify as hazardous waste, EPA must still consider several enumerated factors after finalizing this rule to determine whether the substances are “capable of posing a substantial present or potential threat to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.”
 - Hazardous waste classification triggers RCRA’s cradle-to-grave tracking system and results in cleanup authority under (CERCLA).
- It is unclear when these rules will be adopted.

Validating a PFAS Method

- The challenge: with PFAS already a regulatory challenge, determining whether there is (or is not) PFAS in lubricant matrices is yet another challenge.

Validating a PFAS Method

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 - ASTM E1868-10: Loss on Drying by Thermogravimetry (VOCs in MWFs for SCAQMD Method Rule 1144)

Validating a PFAS Method

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 - ASTM E1868-10: Loss on Drying by Thermogravimetry (VOCs in MWFs for SCAQMD Method Rule 1144)
 - How do we get from having validated methods for PFAS in drinking water (EPA 537.1) or waste water (EPA 1633) (or absorbable organic fluorine (EPA 1621) or ACB B21-02) to a method for lubricant petroleum matrices?

Validating a PFAS Method

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 - ASTM E1868-10: Loss on Drying by Thermogravimetry (VOCs in MWFs for SCAQMD Method Rule 1144)
 - How do we get from having validated methods for PFAS in drinking water (EPA 537.1) or waste water (EPA 1633) (or absorbable organic fluorine (EPA 1621) or ACB B21-02) to a method for lubricant petroleum matrices?
 - Can we use EPA ACB B21-02 as a starting point?

Validating a PFAS Method

- Starting points:
 - EPA 537.1: liquid chromatography (LC)/tandem mass spectrometer (MS, LC-MS/MS for short) method, validated for 18 PFAS in drinking water (537.1, v2.0, 03/20)

Validating a PFAS Method

- Starting points:
 - EPA 537.1: liquid chromatography (LC)/tandem mass spectrometer (MS, LC-MS/MS for short) method, validated for 18 PFAS in drinking water (537.1, v2.0, 03/20)
 - EPA 1633: LC-MS/MS method, validated for 40 PFAS (01/24) in waste water and other matrices

Validating a PFAS Method

- Starting points:
 - EPA 1621: *estimate* absorbable organic fluorine in drinking water using by combustion ion chromatography (01/24: CIC, but short chain ($<C_4$) or long chain ($>C_8$) may have low recoveries, per the method)

Validating a PFAS Method

- Starting points:
 - EPA 1621: *estimate* absorbable organic fluorine in drinking water using by combustion ion chromatography (01/24: CIC, but short chain (<C₄) or long chain (>C₈) may have low recoveries, per the method)
 - EPA ACB B21-02: extracts PFAS from petroleum distillate on to solid phase extraction cartridge (SPE) followed by washing with hexane/ethyl acetate (9:1), extracting with methanol/acetone (9:1) followed by EPA 537.1

Validating a PFAS Method

- What would I do?

Validating a PFAS Method

- What would I do?
 - What are we trying to do?

Validating a PFAS Method

- What would I do?
 - What are we trying to do?
 - I would combine the extraction procedure in EPA ACB B21-02 (extracts PFAS from petroleum distillate on to solid phase extraction cartridge (SPE) followed by washing with hexane/ethyl acetate (9:1), then extracting with methanol/acetone (9:1)), followed by EPA 1633)
 - Result: determine if 40 PFAS are in a lubricant matrix.

Validating a PFAS Method

- How could we do that?

Validating a PFAS Method

- How could we do that?
 - Name *ad hoc* task group to develop budget
 - Gain ILMA BOD support
 - Write RFP, solicit proposals
 - Select contract lab to develop method
 - Convert method to ASTM method
 - Conduct ASTM inter-laboratory study

Validating a PFAS Method

- What do you think?



Proposed Rule 1435 – Control of Toxic Air Contaminant Emissions from Metal Heating Operations

Presentation made to ILMA MWF Committee at 2023 Annual Meeting

4 working Group Meetings to date, last meeting was November 16, 2023

SCAQMD proposed several control strategies at WG Meeting #4

- **Full enclosures for furnaces with HEPA filters**
- **Wet Scrubbers on Quench tank exhausts**

WG Meeting #5 will lay out proposed rule language – Date for this meeting not set at this time



Proposed Rule 1435 – Control of Toxic Air Contaminant Emissions from Metal Heating Operations

Proposed to Regulate two (2) point sources:

- 1. Furnaces operating above 1250°F**
- 2. Quench tanks associated with those furnaces**

Issue is creation of Chromium VI (hexavalent Chromium) from Chromium 0 or Chromium III



Proposed Rule 1435 – Control of Toxic Air Contaminant Emissions from Metal Heating Operations

California Metal Coalition (500 members) is actively lobbying against this rule

The impact of this Rule could result in a significant cost burden for heat treaters in the SCAQMD

Impact of creating hexavalent chromium from furnaces has global implications

For reference, quenching is a MWF operation – thus of interest to this Committee

Proposed Rule 1435 likely to become law by First Quarter 2025

Proposed Amended Rule 1171 Solvent Cleaning Operations



First Adopted August 2, 1991

Last Amended May 1, 2009

SCAQMD is updating and reviewing two chemicals:

- **4-chloro- α,α,α -trifluorotoluene (PCBTF)** **CAS# 98-56-6**
- **tert-butyl acetate (TBAC)** **CAS# 540-88-5**

For a potential ban for the manufacturing and use of these chemicals in cleaning solvents.

Working Group Meeting #1, not yet scheduled.

California Senate Bills 253 and 261

- **SB 253 - Climate Corporate Data Accountability Act, CCDAA**
- **SB 261 - Climate-Related Financial Risk Act, CRFRA**
- *Governor Newsom signed both SB 253 and SB 261 into law on October 7, 2023.*

SB 253

Who will be required to disclose?	Public/private entities formed in the U.S. with annual revenues <u>in excess of</u> \$1 billion and business in the state of California
What will be required to disclose?	Scopes 1, 2 and 3 GHG emissions for the prior fiscal year
How to disclose?	Report to an "emissions reporting organization"
Alternatives for compliance?	None
At what cadence?	2026 (Scopes 1 & 2 for FY25) 2027 (Scope 3 for FY26) Annually thereafter
Assurance	Scopes 1&2 <ul style="list-style-type: none"> • 2026 – Limited Assurance • 2030 – Reasonable Assurance Scope 3 <ul style="list-style-type: none"> • 2030 – Limited Assurance

SB 261

Who will be required to disclose?	Public/private entities formed in the U.S. with annual revenues <u>in excess of</u> \$500 million and business in the state of California
What will be required to disclose?	Climate-related financial risks in accordance with TCFD & measures taken to mitigate/adapt to these risks
How to disclose?	Prepare and publish a publicly available report on company's internet website
Alternatives for compliance?	Provide required disclosures to the best of the entity's ability and explanations for gaps and steps to be taken to fully comply
At what cadence?	2026 and biennially thereafter
Assurance	N/A

TCFD = Task Force on
Climate-related Financial Disclosures

California Senate Bills 253 and 261

Complaint Filed
January 30, 2024

Rule May Be delayed
As The Complaint
Works Its Way Through
The Courts

14 15 16 17 18 19 20 21 22 23 24 25 26 27 28	IN THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, CALIFORNIA CHAMBER OF COMMERCE, AMERICAN FARM BUREAU FEDERATION, LOS ANGELES COUNTY BUSINESS FEDERATION, CENTRAL VALLEY BUSINESS FEDERATION, and WESTERN GROWERS ASSOCIATION, Plaintiffs, v. CALIFORNIA AIR RESOURCES BOARD, LIANE M. RANDOLPH, in her official capacity as Chair of the California Air Resources Board, and STEVEN S. CLIFF, in his official capacity as the Executive Officer of the California Air Resources Board. Defendants.	CASE NO. 2:24-cv-00801 COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF
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Some Issues of the Complaint

94. S.B. 261 requires companies to make public statements estimating their future risk from climate change. This speech is necessarily speculative because it requires companies to estimate not only their risk of damage from future events like natural disasters, but also to speculate about whether those events will occur and will do so as a result of climate change. And it is a politically controversial topic about which significant uncertainty is inevitable.

Some Issues of the Complaint

95. S.B. 261 also fails to describe its key term—“climate-related financial risk”—with enough specificity to enable companies to comply. The term is so ambiguous that companies will be forced to make high-stakes, public guesses about their future—with the aim, on the part of the State, to discourage investors and consumers from doing business with the companies based on that speculation.

Some Issues of the Complaint

96. S.B. 253 requires companies to make public statements not only about their greenhouse-gas emissions, but also about the emissions of up- and downstream entities with which they do business. Because companies must report these Scope 3 emissions as their *own* emissions, the law necessarily requires that a company falsely and inaccurately represent the provenance of these emissions.

97. Moreover, this compelled speech requires companies to speculate about Scope 3 emissions. Calculating Scope 3 emissions is a subjective undertaking, requiring myriad judgment calls about how to identify and quantify another entity's emissions. Alternatively, companies will be forced to demand information from their non-covered partners in the supply chain. Reporting companies under S.B. 253 might disagree with how upstream and downstream entities calculated their emissions, and thus may be forced to convey speech with which they disagree.

Securities and Exchange Commission Activity

FACT SHEET

**The Enhancement and
Standardization of
Climate-Related
Disclosures: Final Rules**



NEW Rule is
880 pages: Includes:
Scope 1 and Scope 2

Does Not Require
Scope 3 Emissions

On March 6, 2024, the Securities and Exchange Commission adopted final rules to require registrants to disclose certain climate-related information in registration statements and annual reports. The Commission [proposed the rules](#) on [March 21, 2022](#). The public comment file is [available online](#).

Updates

TSCA Fee Increases Final Rule

- Under 2016 Lautenberg Amendments to the Toxic Substances Control Act (TSCA), EPA is authorized to collect fees to offset up to 25% of TSCA's implementation costs.
 - 2018: EPA promulgated final rule establishing TSCA fees.
 - 2021: EPA released NPRM amending 2018 final rule.
 - 2022: EPA released SNPRM amending 2021 NPRM.
 - 2024: Final TSCA Fee Increases Rule published.
 - 20% reduction in TSCA costs compared figures proposed in 2022 SNPRM.

TSCA Fee Increases Final Rule

Fee category	Current Fees*	Final Fees**
§4 Test Order	\$11,650	\$25,000
§4 Test Rule	\$35,080	\$50,000
§4 ECA	\$27,110	\$50,000
§5 PMN, consolidated PMN, SNUN, MCAN, consolidated MCAN	\$19,020	\$37,000
§5 LoREX, LVE, TME, Tier II exemption, TERA, Film Articles	\$5,590	\$10,870
§6 EPA-Initiated Risk Evaluation	Two payments resulting in \$2,560,000	Two payments resulting in \$4,287,000
§6 MRRE on Chemical Included in TSCA Work Plan	Two payments of \$945,000, with final invoice to recover 50% of actual costs	Two payments of \$1,414,924, with final invoice to recover 50% of actual costs
§6 MRRE on Chemical Not Included in TSCA Work Plan	Two payments of \$1.89M, with final invoice to recover 100% of actual costs	Two payments of \$2,829,847, with final invoice to recover 100% of actual costs

* The current fees reflect an adjustment for inflation effective January 1, 2022.

** Does not include ~80% discount for small businesses.

TSCA Fee Increases Final Rule

- Small Business Discount
 - Final rule provides an approximately 80% fee discount to companies that qualify as a “small business concern,” (as defined at 40 CFR 700.43) and an extended timeline to remit fees.
 - Depending on NAICS code, less than 500 – 1000 employees.

Fee Category	Final Fees
Test Order	\$5,000
Test Rule	\$10,000
ECA	\$10,000
PMN and consolidated PMN, SNUN, MCAN, and consolidated MCAN	\$6,480
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles	\$2,180
EPA-Initiated Risk Evaluation	\$857,400

TSCA Fee Increases Final Rule

- Other Notable Features
 - Six fee exemptions from EPA-initiated risk evaluations or test rules
 - Byproducts
 - Articles
 - Impurities
 - Non-isolated intermediates
 - Small quantities used for research and development
 - Low volumes
 - Cost-sharing for EPA-initiated risk evaluations
 - Requiring the top 20th percentile of manufacturers to evenly split 80% of the total fee.
 - If three or fewer manufacturers are identified for a substance, EPA will distribute the fee evenly among those three or fewer fee payors, regardless of production volume.

Used Drum Management & Reconditioning ANPRM

- In August 2023, EPA released an advanced notice of proposed rulemaking indicating that the Agency is considering:
 - Redefining the RCRA-empty container provision by lowering or eliminating the current one-inch residue threshold for 55-gallon drums and the 3% by weight limit for IBCs
 - Add a requirement for generators to rinse used or empty drums and totes prior to their shipment to reconditioners
 - Requiring generators and transporters to adopt more stringent packaging and inspection practices
- Overwhelming majority of commenters argued that RCRA empty container provision should not be amended
 - EPA's concerns can be effectively addressed by working with industry to develop best practices guidance
- No timeline provided in the Fall 2023 Unified Agenda
 - EPA will be reviewing comments first half of 2024

Formaldehyde

- EPA Formaldehyde *draft* Risk Assessment published March 15th
 - “In this draft risk evaluation, **EPA preliminarily finds that formaldehyde presents an unreasonable risk of injury to human health**”
 - While lubricant and lubricant manufacturing are cited many times, Howard Cohen study appears not to be included

Formaldehyde

- ACC Comments in letter of March 25th
 - Instead of virtual peer review meetings (now scheduled for May 20-23), hold in-person meeting
 - Extend public comment period beyond sixty days (May 14th to June 13th or later to include at least two weeks following peer review meeting)

Formaldehyde

Key Points: Occupational Exposure Assessment for Formaldehyde

- EPA estimated occupational exposures to formaldehyde through air (inhalation) and skin contact (dermal) routes. EPA estimated both high-end and central tendency exposure estimates for occupational exposure scenarios (OESs) associated with each Toxic Substances Control Act (TSCA) condition of use (COU).

Formaldehyde

Key Points: Occupational Exposure Assessment for Formaldehyde

- Exposure for most OESs were estimated based on monitoring data. For OESs that lacked available monitoring data, EPA applied Monte Carlo statistical modeling approaches to estimate exposures.

Formaldehyde

Key Points: Occupational Exposure Assessment for Formaldehyde

- In general, air concentrations in workplaces are higher than ambient air (outdoor) concentrations.
- The full-shift inhalation exposure estimates for the OESs ranged from 0.006 to 0.6 ppm for central tendency exposures and 0.006 to 14 ppm for high-end exposures. The dermal exposure estimates ranged from 0.56 to 840 $\mu\text{g}/\text{m}^3$ for central tendency exposures and 0.84 to 3,090 $\mu\text{g}/\text{m}^3$ for high-end exposures.

Formaldehyde

From Executive Summary:

- EPA has a high level of certainty that 41 occupational conditions of use and has less certainty that 5 additional occupational conditions of use contribute to unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with **acute inhalation** of formaldehyde;

Formaldehyde

From Executive Summary:

- EPA has a high level of certainty that 10 occupational conditions of use and has less certainty that 35 additional occupational conditions of use contribute to the unreasonable risk due to non-cancer effects—specifically respiratory and non-respiratory health effects in workers, including reduced pulmonary function, increased asthma prevalence, reduced asthma control, allergy-related conditions, male and female reproductive toxicity, and developmental effects, associated with **chronic inhalation** exposures

Formaldehyde

PUBLIC RELEASE DRAFT – DO NOT CITE OR QUOTE
March 2024

Condition of Use (COU)			Occupational Exposure Scenario (OES) Mapped to COU
Life Cycle Stage	Category	Subcategory	
Processing	Incorporation into an article	Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	Composite Wood Product Manufacturing
			Paper Manufacturing
			Plastic Product Manufacturing
			Other Composite Material Manufacturing
Processing	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; petroleum and coal products manufacturing	Processing of Formaldehyde into Formulations, Mixtures, or Reaction Products
	Incorporation into a formulation, mixture, or reaction product	Asphalt, paving, roofing, and coating materials manufacturing	
	Incorporation into a formulation, mixture, or reaction product	Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	
	Incorporation into a formulation, mixture, or reaction product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing	

Formaldehyde

If in the final TSCA risk evaluation for formaldehyde, EPA determines that formaldehyde presents an unreasonable risk of injury to health or the environment under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk.

ASTM Update

E34.50 – Health & Safety Standards for MWFs

- WK88295 - E2693-2019 Practice for Prevention of Dermatitis in the Wet Metal Removal Fluid Environment - John and Ann Ball reviewing/revising for Spring ballot
- WK68411 New Standard Minimizing Heavy Metal Accumulation in Metalworking Fluids (Technical Contact: Rick Butler)
- WK80871 New Standard Evaluating Water-Miscible Metalworking Fluid Foaming Tendency by Recirculation testing (Technical Contact: Stefanie Velez)
- WK86561 New Standard Non-Animal Acute Toxicity Testing of Water-Dilutable Metalworking Fluids - John and Pat Kempl to draft new standard

ASTM Update

E50 – Committee on Environmental Assessment, Risk Management and Corrective Action

- E50.04 on Corrective Action
 - E3302-24 – Guide for PFAS Analytical Methods Selection
- E50.07 on Climate and Community
 - E3377-24 – Guide for Environmental, Social and Governance (ESG) Disclosure Related to Climate and Community

Chlorinated Paraffins

- CPIA Completed MCCPs Testing (as Required by SNUR) and Submitted Data to EPA
 - No Timeline from EPA New Chemicals Group on Completing Review/Evaluation
 - No Additional Testing Planned
- Stockholm Convention Evaluation of MCCPs
 - EPA International Office Active
 - Proposed Exemptions for MCCP Uses in MWFs for Certain Applications (Aerospace & Defense)
 - Outcome Could Affect EPA Decision making
- EU
 - SVHC Listing Followed By Restriction Proposal
 - Recommendation for 10-Year Phaseout Period for All MWFs
 - European Commission Expected to Adopt Recommendation Soon

Thank you!

Questions & Comments?

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