2018 ANNUAL MEETING
Metalworking Fluid Committee
October 8th, 2018
The Regulatory Environment for Metalworking Fluids in UK and Europe

8th October 2018
the voice of the UK Lubricants Industry
the voice of the UK Lubricants Industry

UNITED KINGDOM LUBRICANTS ASSOCIATION

UKLA METALWORKING FLUID PRODUCT STEWARDSHIP GROUP

Formed in the 1990s as a group representing the manufacturers, suppliers of additives and preservatives used in metalworking fluids and representatives from the UK HSE, UK Government Health and Safety Laboratory.

The Metalworking Fluid Product Stewardship Group brings together those companies with a commitment to the development, manufacture and marketing of safe and effective MWF products.

The Group intends to assist in the education of end users, enhance the health and safety provision to both the members and their customers’ employees, consider the protection of the environment and provide qualified, reviewed information to industry, trade unions, government and the general public.
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UKLA METALWORKING FLUID PRODUCT STEWARDSHIP GROUP

Afton Chemical/Italmatch
Arizona
Ashland (formerly ISP)
Blaser Swisslube
Cimcool
Condat
Croda
Fuchs Lubricants
Hornett Bros
Houghton
Lonza
Lubrizol
Macdermid

Morris Lubricants
Pennine
Quaker
Q8
Schulke
Total
Troy

UK Government:
Health & Safety Executive
Health & Safety Laboratory

www.ukla.org.uk
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The Environment

- Operator Health & Safety
- Environmental Issues
- Regulatory Environment
- MWFPSG
- Product Safety
- Operational Safety
- Political Environment
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2001 White Paper

Global chemical production has risen from 1 million tonnes in 1930 to 400 million tonnes today. In the EU 100,000 different substances registered. In 1998 the EU was the world’s largest chemical industry with a 31% market share followed by the US with 28% of production value.

Certain chemicals cause serious damage to human health. Asbestos is known to cause lung cancer and benzene leads to leukaemia.

Though these substances have been banned or subjected to other controls, measures were not taken until after the damage was done because knowledge about the adverse impacts of these chemicals was not available.
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**REACH – EC 1907/2006**

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) aims to improve the protection of human health from the risks posed by chemicals.

Applies to all chemical substances.
Places the burden of proof on companies to identify and manage risks to users
If the risks cannot be managed, authorities can restrict use.

It entered into force on 1 June 2007.
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**REACH**

Manufacturer: If you make chemicals, either to use yourself or to supply to other people (even if it is for export), then you will probably have some important responsibilities under REACH.

Importer: If you buy anything from outside the EU/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onwards sale or finished products, like clothes, furniture or plastic goods.

Downstream users: Most companies use chemicals, sometimes even without realising it, therefore you need to check your obligations if you handle any chemicals in your industrial or professional activity. You might have some responsibilities under REACH.
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**REACH – Updates**

EC 1354/2007 (Enforcement)
EC No 1272/2008 (CLP)
EC No 453/2010 (Safety Data Sheets)
EC No 987/2008 (REACH Exceptions)
EC No 134/2009 (Testing Requirements)
EC No 143/2011 & 348/2013 (Authorisation)
EC No 552/2009 & 276/2010 (Restrictions)
EC No 2016/9 (Cost Sharing)
EC No 2018/4 Nanomaterial Annexes
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REACH - Issues

*Under the REACH Regulation all substances produced or imported into the EU in quantities over 1 metric ton per year (per legal entity) need to be registered.*

*Registration is made per substance & per legal entity*

*NO REGISTRATION = NO MARKET*

*Companies are expected to work together in consortia to register substances*
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Following Registration the ECHA Evaluates the submitted dossiers

According to the 2016 ECHA evaluation Report

85% received quality observation letters (Draft Decision)

-> 181 dossiers evaluated in 2016
-> 234 dossiers carried over from 2015
-> Majority of checks carried out on priority substances
-> Majority of compliance checks that resulted in a DDR had to do with testing proposals and the requirement for additional / testing or support of the testing strategy.
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Fees are set by the ECHA that all registrants need to pay to continue to produce/market a substance in the EU.

<table>
<thead>
<tr>
<th>Tonnage band*</th>
<th>Standard</th>
<th>Medium</th>
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*As per EC 2015/867 for a Joint Submission SME as defined by 2003/361/EC
Depending of tonnage band the number of test study endpoints varies (phys-chem data to multiple generation gene-tox studies)

<table>
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<tr>
<th>Tonnage</th>
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<th>Estimated Fleischer Cost</th>
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<td>28</td>
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* Fleischer 2005 adjusted study costs
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Registrations are submitted to the European Chemicals Agency (ECHA)

Only EU companies can submit a registration.

- Non EU manufacturers that import to the EU need to appoint a “REACH only representative” to act on their behalf.

Registration dossiers are submitted via the ECHA online portal “REACH-IT”

Registration dossiers include information on substance identification, manufacturing processes, test results, evaluations on the impact on humans and the environment, safe use, etc.
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**Cost impact of REACH on lubricating greases** *

Grease thickeners are comparatively low volume chemicals.

The cost impact of REACH increases with the reduction of produced volumes.

Since 2008 Members of the European Grease Thickeners Consortium have contributed more than 5 million Euros in REACH related activities.

For each substance group the required testing program (data set) ranges between 300,000 – 450,000 Euros.

* Eldon 2017
The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) is based on the United Nations’ Globally Harmonised System (GHS) and its purpose is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.

One of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a hazardous classification. In this context, classification is the starting point for hazard communication.
Once a substance or mixture is classified, the identified hazards must be communicated throughout the supply chain, including consumers. Labelling and Safety Data Sheets allows the hazard classification to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.

CLP sets detailed criteria for the labelling elements for hazard, prevention, response, storage and disposal, for every hazard class and category. It also sets general packaging standards to ensure the safe supply of hazardous substances and mixtures.
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**Harmonised classification and labelling**
The classification and labelling of certain hazardous chemicals is harmonised to ensure adequate risk management throughout the EU.

**Alternative chemical names in mixtures**
Suppliers can request the use of an alternative chemical name for a substance present in a mixture, to protect the confidential nature of their business, and their intellectual property rights.

**C&L Inventory**
Under CLP, manufacturers and importers must submit classification and labelling information for the substances they are placing on the market to the C&L Inventory held by ECHA.

**Poison centres**
A new Annex was added to the CLP Regulation in 2017, harmonising notifications under Article 45 to provide standardised reporting for emergency health response.
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**BPR**

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection. The regulation has been applicable from 1 September 2013.

All biocidal products require authorisation before they can be placed on the market, and the active substances contained in the product must have been previously approved. Products containing new active substances still under assessment may also be allowed on the market where a provisional authorisation is granted.

The BPR aims to harmonise the market at Union level; simplify the approval of active substances and authorisation of biocidal products; and introduce timelines for Member State evaluations, opinion-forming and decision-making.
Nanomaterials
EU definition 1 to 100 nanometers

Incorporated into REACH Annexes
Rapidly expanding area of science
Concern about the impact on human health
EU Established Nano Observatory in 2017

17th July ECHA identified key parameters for future market studies:
  Market analysis by segmentation, such as by geographical region, application, end use or nanomaterial type.
  Market forecasts and compound annual growth rate (CAGR).
  Market share by region, country or company.
  Market trends, such as consumption and demand.
  Competitive scenarios and product portfolios of key vendors.
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Circular Economy

From a linear to a circular economy
Lubricants Absolute Hazard

GEIR proposes the following approach:
By 2020: An EU-wide target of 95% collection of waste oils of the produced and collectable waste oil in each Member State;
An EU-wide target of reaching at least 60% of re-refined waste oils of the produced and collectable waste oil in all Member States (target 1);
By 2025: An EU-wide target of 100% collection of waste oils of the produced and collectable waste oil in each Member State;
An EU-wide target of 85% of re-refined waste oils of the produced and collectable waste oil in all Member States (target 2);
Member States that have no waste oil regeneration facility shall be deemed to achieve these regeneration targets by exporting the collected waste oil from their country.
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Any Questions?
Chlorinated Paraffin Update

For ILMA Metalworking Fluids Committee Meeting
October 8, 2018
Topics

- New CP Substances SNURs
  - SNUR update
  - Comments on SNURs
- Next Steps with EPA
  - Test program on MCCP
  - Status of Existing CP Substances
- TSCA Fee Rule
New CP Substances SNUR

- Significant New Use Rules (SNUR) on 10 new CP substances published on August 17, 2018 as proposed rules and direct final rules.
  - New chemicals include MCCP, LCCP and vLCCP range substances.
  - Previously added 3 vLCCPs not part of this SNUR.
  - The direct final rules would have become effective if there were no adverse comments. They will now be withdrawn.
- Metalworking fluid applications permitted for all new CP substances (i.e. not a “new use”)
- SNURs were intended to make the consent order (CO) requirements applicable to all, though SNUR language was not consistent.
EPA MCCP Testing Program

- Technically required of all recently approved CPs, regardless of chain-length.
- Biodegradation
  - OECD 308 sediment simulation studies on C14, 56% Cl (wt.) and C16, 56% Cl (wt.)
- Aquatic Toxicity
  - OECD 225 sediment-water Lumbriculus and OECD 211 chronic daphnia studies on C14, 30% Cl (wt.)
  - If adverse effects are observed in C14 studies above the triggers, run same tests with C16, 56% Cl (wt.)
- Bioaccumulation Testing
  - Only if adverse effects are seen in toxicity studies
  - OECD 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes and OECD 305: Bioaccumulation in Fish in C16, 56% Cl (wt.)
Comments on CP SNURs

- Comments were submitted by ILMA, ACC (on behalf of the coalition), CPIA, Chemical Users Coalition (CUC), Aerospace Industries Association (AIA), Dow Chemical and EDF.

Concerns include:
- EPA’s treatment of these as new chemicals, especially given the chemicals have already been on the market for >5 years (ACC, ILMA, AIA, Dow, CUC)
- Inconsistencies between COs and SNUR (all)
- EPA approving PMNs for PBT substances (EDF) (note: EDF cites ILMA press release)
Next Steps on CP SNURs

- Further interaction with EPA is likely going to be needed to resolve the issues.
  - This could be part of a larger conversation concerning treatment of both new and existing CP substances.
- Coalition is planning to meet in October 2018 to discuss possible next steps.
- Need ILMA involvement to continue!
Existing CP Substances

- All existing CP substances remain on the TSCA inventory and several are on the active exempt list.
- Limited formal regulatory action has been taken on existing CP substances, except:
  - SNUR on Alkanes, C12-13, chloro
  - HPV Test Rule on Alkenes, C12-24, chloro
- Considering options for how best to interact with EPA on these substances.
- Need to achieve some sort of level playing field between new and existing CP substances.
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<tr>
<th>Chemical Name</th>
<th>CAS RN</th>
<th>TSCA Inventory Status</th>
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<td>Paraffin waxes and Hydrocarbon waxes chlorinated</td>
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<td>UVCB, Active</td>
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<td>Alkenes, C12-24, chloro</td>
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<td>UVCB, T, Active</td>
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<td>Alkenes, polymerized, chlorinated</td>
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<td>UVCB, XU, Active</td>
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<td>Alkanes, C6-18, chloro</td>
<td>68920-70-7</td>
<td>UVCB, Active</td>
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<td>Alkanes, chloro</td>
<td>61788-76-9</td>
<td>UVCB, Active</td>
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</tbody>
</table>

CPIA Update to ILMA MWF Committee
TSCA Fee Rule

- Final rule released in October 2018.
- PMN fee has gone up to $16K
  - Probably the least controversial aspect of the rule
- EPA is also imposing fees for Section 4 (testing) and Section 6 (existing chemical) regulatory actions:
  - Section 4: $9.8K to $29.8K
  - Section 6: $1.35 million for EPA initiated action on TSCA Workplan chemicals
- MCCP and LCCP are on TSCA Workplan
Thank You!

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Washington, DC 20036
Phone: +1.202.419.1504
Email: ajaques@regnet.com
PHOSPHORUS REDUCTIONS
AND POTENTIAL IMPACT ON ILMA MEMBERS

John Burke
Houghton International
Background

• In 2014 City of Toledo issued a “do no drink / do not boil” water alert that lasted for three days.

• Toledo’s drinking water supply is from Lake Erie and supplies 500,000 people

• The alert was to the elevated levels of cyanobacteria also known as toxic blue green algae.

• 11,000,000 people get their drinking water from Lake Erie
Background

• Cyanobacteria produce microcystins, some of which are toxic and persist for months or years.

• The toxic algae / cyanobacteria / microcystins were directly related to high levels of phosphorus.

• The predominant source of phosphorus is from agricultural runoff, although there is a contribution from Industry, albeit small.
Phosphorus

• Farmers / Agricultural have been under voluntary initiatives to reduce phosphorus into Lake Erie, but the levels have been steadily rising for the last 15 years.

• Algae blooms are not new to Lake Erie; they have occurred there as early as the 1950’s. The blue-green algae were likely present at that time along with toxic microcystins, but the analytical methods were not yet available to measure these toxins in the parts per billion range.
Phosphorus

• Significant algae blooms are not limited to the western basin of Lake Erie. These algae blooms have occurred in surface waters of the Gulf of Mexico, Chesapeake Bay, Indian Lake (Ohio), Grand Lake St. Mary (Ohio), Lake Okeechobee (Florida) and the west coast of Florida south of Tampa, continuing for 150 miles southward. Algae blooms are actually a global issue.
Phosphorus

• It is well-documented that high levels of certain forms of phosphorus as well as some forms of nitrogen contribute to algae blooms.

• Some industrial sources include (but are not limited to) lubricant additives and surface-coating pretreatment processes. Lubricant additives can be phosphorus, phosphite and phosphide. Surface coating pre-treatments can be iron phosphate, zinc phosphate, and to a lesser degree zirconium phosphate.

• Phosphates and complex poly-phosphates can be used in industrial detergents and cleaning compounds, however their use has voluntarily diminished over the past 30+ years.
Nitrogen also Contributes

• Nitrogen sources are common in water-diluted metal removal fluids, metal forming fluids and metal treatment fluids. The most common nitrogen sources in these fluid are from alkanolamines (typically monoethanolamine, triethanolamine, and monoisopropanolamine). These alkanolamines are 100-percent water soluble and as such are difficult to separate from the water phase.
Regulatory

• In 2017 the US EPA and Canada EPA agreed to a 40 percent voluntary reduction of phosphorus loading into the western basin of Lake Erie by 2025 from a baseline year of 2008.

• With the recent issue that occurred in Toledo in 2014, there is a renewed interest in the reduction of phosphorus in Lake Erie. Reductions in nitrogen were also discussed, but the current focus is still reduction of phosphorus.
Regulatory

• On July 11, 2018 Ohio Governor John Kasich took matters into his own hands with an executive order regarding agricultural pollution feeding Lake Erie’s chronic toxic algae problem.

• Under this executive order, his administration asked the Ohio Soil and Water Conservation Commission to designate eight watersheds or portions of watersheds with high phosphorous levels within the Maumee River Basin as “distressed.” Distressed status of a waterway prohibits additional phosphorus loading from agricultural or industrial sources.
Regulatory

• Overall, this is good news for industry since this executive order and subsequent activities address the primary loading source of phosphorus (agriculture). However, unlike a law passed by the legislature, an executive order survives only as long as the governor wills it.
Potential Next Steps

• Separate Industry from Agriculture loading focus
  • Industry is a de Minimis source.

• Not all sources of phosphorus are contributory
  • Dissolved reactive phosphorus (DRP) is the issue
  • Complex phosphorus sources in lubricants may not contribute to algae growth.

• Industry should also be ready to demonstrate that nitrogen from alkanolamines is not a contributor to algae growth, if possible.
Potential Next Steps

• The MWF committee needs to determine the next steps, if any, and make recommendations to ILMA’s Board of Directors.
2018 ANNUAL MEETING
Metalworking Fluid Committee
TSCA – Inventory Reset & Nomenclature Issues

John Howell, Jeff Leiter, Andrew Jacques
Timeline - Retrospective Reporting (Form A)

- Manufacturer (& processor) submission period: 8/12/2017 - 2/7/2018
- Processor submission period: 3/2018 - 10/5/2018

EPA publishes draft inventory with substances reported by 2/7/2018 designated as “active”
Timeline - Future Reporting (Form B)

11/2018

EPA publishes initial inventory with substances reported by 10/5/2018 designated as either “active” or “inactive"

2/2019

date when substances designated as “inactive” become effectively “inactive”
Active/Inactive Inventory

https://www.epa.gov/tsca-inventory/tsca-inventory-notification-active-inactive-rule
<table>
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<tr>
<th>ID</th>
<th>CASRN</th>
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## Active/Inactive Inventory

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<td>Fatty acids</td>
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<td>Fatty acids, reaction products with triethanolamine</td>
<td>Anhydride.</td>
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<tr>
<td>3973</td>
<td>126-86-11</td>
<td>Fatty acids, reaction products with triethanolamine, anhydride.</td>
<td>Reaction product.</td>
</tr>
<tr>
<td>3974</td>
<td>126-86-12</td>
<td>Fatty acids, reaction products with triethanolamine, anhydride.</td>
<td>Reaction product.</td>
</tr>
<tr>
<td>3975</td>
<td>126-86-13</td>
<td>Fatty acids, reaction products with triethanolamine, anhydride.</td>
<td>Reaction product.</td>
</tr>
<tr>
<td>3976</td>
<td>126-86-14</td>
<td>Fatty acids, reaction products with triethanolamine, anhydride.</td>
<td>Reaction product.</td>
</tr>
</tbody>
</table>

**Note:** The table continues with similar entries for other compounds and their descriptions.
Nomenclature Guidance

https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting
Nomenclature Guidance

- **Class 2 Organic Chemical Substances**
  - Cannot be represented by a definite molecular formula
  - Substitute:
    - “alkyl” for “methyl,” “ethyl” or “propyl”
    - “plant-based oils” for “oils, catnip”
    - “Animal-based fatty acid salts” for “fatty acids, tallow, sodium salts”
  - Many, many more examples in EPA document
Nomenclature Issues

- How many other chemical names exist in the active inventory that EPA will consider “too generic?”
  - Example: “Benzene sulfonic acid, alkyl derivatives”
BIOCIDES UPDATE

ILMA 2018 ANNUAL MEETING
MWF COMMITTEE MEETING
1,2-BENZISOTHIAZOLINONE SUPPLY ISSUE

- USERS WILL BE AWARE OF A GLOBAL SUPPLY DISRUPTION
- DRIVER WAS CHINESE GOVERNMENT’S “BLUE SKY” ENVIRONMENTAL INITIATIVE
- RESULTED IN PRODUCTION STOP OF THE PRECURSOR (ortho-chloro-benzonitrile)
- LIMITED PRODUCTION OF OCBN HAS NOW RESTARTED.
- SITUATION IS EXPECTED TO NORMALIZE BY CALENDAR YEAR END.
- COSTS HAVE INCREASED, AND FURTHER INCREASES ARE EXPECTED.
EUROPE

A REPEAT….

- EFFECTIVE 12/1/2018, THE FORMALDEHYDE CONDENSATES MBM, MBO AND HPT MUST CARRY 1B CARCINOGEN LABELS

- OTHER FORMALDEHYDE-BASED PRODUCTS INCLUDING HHT NOT IMPACTED – EARLIEST DATE FOR SIMILAR LABELING LIKELY 2022 (THREE YEAR REGULATORY IMPLEMENTATION WINDOW)
EUROPE

ECHA

- IS USING BIOCIDES AS A TEST CASE FOR REPRODUCTIVE TOXICANTS
- REQUIRES DEVELOPMENT OF ADDITIONAL INFORMATION ON POTENTIAL ENDOCRINE DISRUPTION.
- WILL AGAIN ADD NEW AND SIGNIFICANT COSTS, AS DATA REQUIREMENTS ARE DIFFERENT TO US EPA REQUIREMENTS.
CHINA TARIFFS

ON THE LIST THAT WENT INTO EFFECT 9/24:
- CMIT/MIT
- OIT
- DBNPA

FUTURE OBVIOUSLY UNCERTAIN RE POTENTIALLY ALL CHEMICALS COMING FROM CHINA, NOT JUST BIOCIDES.
KOREA BPR (NEW) GOES INTO EFFECT 9/1/2019

SOME SIMILARITIES TO EU BPR, SO POSSIBLE THAT EXISTING DOSSIERS MAY BE LARGELY APPLICABLE

DIFFERENT APPROACH RE TREATED ARTICLES

DIFFERENT APPROACH FOR RISK ASSESSMENTS
UPDATE ON PMRA PROPOSED REDUCTION IN USE RATES FOR CIT/MIT (TO 8 PPM ACTIVES).

- STILL WITH PMRA PENDING REVIEW OF DERMAL DATA SUBMITTED.
- IF NO RESPONSE BY DECEMBER LABEL IMPLEMENTATION DEADLINE, MAY HAVE TO GO FORWARD WITH LABELS WITH REDUCED USE LEVELS.
2018 ANNUAL MEETING

Metalworking Fluid Committee

UEIL HSE Update

Stephan Baumgärtel, John Howell
2018 ANNUAL MEETING

Metalworking Fluid Committee

MWF Studies on Autoworkers

John Howell
Papers Reviewed - 2018


Papers Reviewed - 2018

- CA Prop 65, TRIM® VX (May 25th, 2018)
Park, Risk assessment for cancer and metalworking fluid outcomes

- Method: using published data from all of the GM-UAW studies, Park calculated an exposure response for each cancer site. Aggregate excess cancer risk was estimated by applying a lifetable calculation.

- Cancer sites producing the most attributable risk: Larynx, esophagus, brain, female breast, uterine cervix
With constant workplace exposure of 0.1 mg/m³ over 45 years of a working life, risk of attributable cancer was 3.7% or, excluding less certain female cancers, 3.1%.

Park notes that excess cancer risk was calculated to occur at exposures ¼ of NIOSH Recommended Exposure Level. “Because ingredients in certain MWF remain from earlier formulations, it is likely that some MWF carcinogenicity remains today.”
Colin, et al., Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study

- To assess relationship between MWF exposure and bladder cancer, a nested case-control study setup for a cohort of workers from six plants (2006 - 2012).
- Three controls were selected for each bladder cancer case (total cases, 84; total controls, 251); all were interviewed.
- Methods: conditional multiple logistics regression analyses, taking occupational, non-occupational exposures into account 25 years before diagnosis.
Colin, et al., Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study

Results:

- ORs increased significantly with duration of exposure to straight MWFs (OR=1.13 (1.02-1.25)) and increased with frequency-weighted duration of exposure to straight MWFs (OR=1.44 (0.97-2.14)).
Results:

- ORs increased with soluble MWFs but not significantly. No significant association was found with older exposures to MWFs or with exposure to synthetic MWFs.
- The authors note: “The increased risk of bladder cancer observed among workers exposed to straight MWFs and to a lesser extent to soluble MWFs may be explained by the presence of carcinogens (such as PAH) in mineral oils component of straight and soluble oils.”
Hypothesis: unrecognized health hazards exist in currently marketed MWF formulations that are presumed to be safe based on hazard assessments of individual ingredients.

In vivo 13-week inhalation studies were designed to characterize and compare the potential toxicity of four MWFs: Trim VX, Cimstar 3800, Trim SC210, and Syntilo 1023.
Ryan, Kristen R, et al., Comparative pulmonary toxicity of MWFs in rats and mice

- Rats and mice were exposed to MWFs via whole-body inhalation at concentrations of 0, 25, 50, 100, 200, or 400 mg/m3 for 13 weeks; although high concentrations were used, survival was not affected
Data confirm that newer MWFs have the potential to cause respiratory toxicity in workers who are repeatedly exposed via inhalation.

The authors note, “It should be noted that these four MWFs cannot be considered as representative of other MWFs within their respective classes because of the significant variability in MWF formulations.”
CA Prop 65 - TRIM® VX
2018 ANNUAL MEETING

Metalworking Fluid Committee

Discussion