ILMA 2017 Management Forum

Metalworking Fluid Committee Meeting

Park Hyatt Aviara Resort
Carlsbad, CA

April 20, 2017
NAM Manufacturing Summit 2017

- The National Association of Manufacturers Manufacturing Summit 2017 is a great opportunity to convey issues and concerns to elected officials specific to lubricant manufacturers
- Held: June 20-21, 2017 at the Grand Hyatt in Washington, DC
- More information on ILMA’s website
ILMA MWF Committee
20 April 17

F + L Asia Conference
07-10 March 17

UEIL HSE Committee Meeting
24 January 17
F + L Asia

- Primary focus was on automotive – primarily engine oils

- Other than John Burke only two other presentations addressed MWF topics
  - Jimmy Zou – Angus
  - Shana McCabe – Ingevity (formerly McKesson)

- Presentations will be available
F + L Asia

- Jimmy Zou – Angus
  - Commercial presentation
    - Allowed at F+L, tolerated at UEIL
  - Meeting MWF Longevity Requirements without Formaldehyde Condensate Biocides, Boric Acid and Secondary Amines
    - Listed issues with Boric Acid Salts, formaldehyde and secondary amines
      - Boric acid dosage limitations
      - Formaldehyde IARC carcinogen
      - Secondary amines - DCHA classified as “deleterious substance” in Japan
  - Presented the Angus replacement for Corrguard
• Shana McCabe – Ingevity
  – Regulatory Hurdles to Entering a New Market as a Small-Medium Sized Company
    • Variations among fees and required data among regions add to cost
      – Variability regarding animal testing
    • Timing to notify various inventories among regions
      – Can extend to 24 months for approval/listing
      – Guilty until proven innocent
        » Must prove substance safety
        » Research lab consolidation delays testing
      – Different versions of REACH among regions
    • Phase-in particularly difficult
      – Volume-tiered, time-staggered basis no longer available
      – Product will require commercial viability before launch
  • First step is Inquiry Dossier to ECHA
    – Full dossier will have high cost
    – New product launch can cost as much $3MM due to REACH registration
UEIL HSE

• Irritating Salts Project
  – Stearic Acid classification was missing
  – Hazards associated with both skin and eyes

• Discussion regarding whether to consolidate information on one page or have separate page for each classification

• Opted for two pages
UEIL HSE

• REACH Consultation
  – UEIL will not reopen the regulation for amendment
    • Possible unintended/undesired consequences
  – REACH already becoming too complicated
  – Preferred approach will be to attempt to influence enforcement

• Boric Acid
  – No news
UEIL HSE

• EU Ecolabel
  – Includes MWFs
  – “Voluntary policy instruments”
  – Current criteria valid until end of 2018
  – Decreased various fraction from 0.1% to 0.01%
    • Must be included as impurities in the “stated substances” on application
    • Fraction of sensitizing substances 0.01%
  – Appears to affect only neat MWFs – NOT “diluted concentrates (UEIL HSE language)
  – UEIL believes ratio is 60:40 Neat:H$_2$O
    • Has requested input from ILMA
UEIL HSE

- Folding Label
  - UEIL requesting limit of 6 languages
  - Down from 27....
UEIL HSE

• REACH/CLP/Chemicals
  – Several additions
    • perfluorodecanoic acid, 4-Heptylphenol, branched and linear (4-HPbl), & concentrated ammonia salts
  – A number of blenders suspect that chemicals or supplies being led out of the market due to legislation
  – Over 70,000 registrations required nowadays, ECHA has received ~14,000 registrations
  – Includes "intermediates", which are of limited use for lubes (November 2015)
  – Some large chemical manufacturers in Europe have reported production of certain chemicals has been discontinued in Europe
    • Some continue production outside EU
    • Biocides featured
UEIL HSE

- eSDS – extended Safety Data Sheets
  - Will contain an annex with exposure scenarios
  - Describe the conditions under which the chemical can be used safely – includes entire chain
  - Exposure scenarios can, above all, be very extensive if they refer to all the applications of an industrial association of downstream users
  - An extended Safety Data Sheet is required under the following conditions:
    - The SDS is for a chemical that has been registered according REACH with the European Chemicals Agency (ECHA).
    - The chemical is manufactured or imported in quantities > 10T / yr.
    - The chemical is classified as hazardous.
  - ATIEL has criteria for exposure scenarios
  - BASF has written a good summary
UEIL HSE

• OTHER ISSUE - SHERA

  – Polycyclic Aromatics in used engine oil deemed carcinogenic.
  – Probability of skin contact by workers in oil change operations (especially quick lube shops) could create a huge issue.
  – Defining the conditions is seen as a problem as finding measurable chemistry and/or establishing time of use will be difficult.
  – And finally…
  – Thanks for your patience
ILMA MWF Committee
April 20, 2017

Fuels and Lubes Asia Meeting
March 7 – 10, 2017

MWF Presentations by John Burke
Houghton International
MWF Presentations

Two Presentations

– *Regulatory Decisions That Will Affect Metalworking Fluid Selection and Use*
  - 3.5 hours, 255 slides

– *Five Key Trends That Leaders Need to Know About the Future of Metalworking Fluids*
  *• 0.5 hours, 35 slides*
Regulatory Decisions That Will Affect Metalworking Fluid Selection and Use

Topics Included, but not limited to:

• Biocides
• Formaldehyde
• Chlorinated Paraffins and Alternatives
• Boric Acid, Cobalt, Titanium dioxide, Respirable Silica, and more
• Volatile Organic Compounds
• Phosphorus, Phosphates, and Nitrogen
• Toxic Metal Emissions from Dry Machining
• California Proposition 65
• Globally Harmonized System (GHS)
• TSCA Reform, REACH, K-REACH, Australia REACH, etc.
Five Key Trends That Leaders Need to Know About the Future of Metalworking Fluids

MQL and Dry Machining
  – Danger ahead?

Bio based lubes
  – Growing but not that green

Fuel Economy demands – Auto Industry
  – Possible 40% reduction in MWF in 10 years

Recycling MWF pays off – fast
  – Easy 35% reduction in MWF, 2.0 year ROI

Reach and GHS and Social Media
  – People are actually reading your SDS
    • TEA / DEA, cancer and CA Prop. 65 example
  – Too much visibility via social media
ILMA MWF Committee
April 20, 2017

SCAQMD Rule 1430 - UPDATE

Control of Emissions from Grinding Operations at Metal Forging Facilities
SCAQMD Rule 1430

Background:

- Rule went into effect on March 3, 2017
- Direct impacts 22 Forge plants in the South Coast Air Quality Management District (four counties)

Rule requires:

- Complete enclosure of metal grinding operations
- Monitoring
- Record Keeping
- Mass Balances of production volumes versus emissions
- Costly and operationally demanding
SCAQMD Rule 1430

Included:
• Dry grinding and metal cutting operations
• Minimum Quantity Lubrication operations

Exempted:
• Flood Coolant Application
SCAQMD Rule 1430

• “The purpose of this rule is to reduce toxic emissions, particulate matter emissions, and odors from metal grinding and metal cutting operations at metal forging facilities”

• Concern is primarily Ni and Cr

• Further concern is identification of Cr$^{+6}$ in emissions at and beyond the property line at one forge facility
Health Effects of Hexavalent Chromium

Hexavalent chromium is a toxic form of the element chromium. Hexavalent chromium compounds are man-made and widely used in many different industries.

Some major industrial sources of hexavalent chromium are:
- chromate pigments in dyes, paints, inks, and plastics
- chromates added as anti-corrosive agents to paints, primers and other surface coatings
- chrome plating by depositing chromium metal onto an item's surface using a solution of chromic acid
- particles released during smelting of ferrochromium ore
- fume from welding stainless steel or non-ferrous chromium alloys
- impurity present in portland cement.

How hexavalent chromium can harm employees

Workplace exposure to hexavalent chromium may cause the following health effects:
- lung cancer in workers who breathe airborne hexavalent chromium
- irritation or damage to the nose, throat, and lung (respiratory tract) if hexavalent chromium is breathed at high levels
- irritation or damage to the eyes and skin if hexavalent chromium contacts these organs in high concentrations.

How hexavalent chromium affects the nose, throat and lungs

Breathing in high levels of hexavalent chromium can cause irritation to the nose and throat. Symptoms may include runny nose, sneezing, coughing, itching and a burning sensation.

Repeated or prolonged exposure can cause sores to develop in the nose and result in nosebleeds. If the damage is severe, the nasal septum (wall separating the nasal passages) develops a hole in it (perforation).

How employees can be exposed to hexavalent chromium

Employees can inhale airborne hexavalent chromium as a dust, fume or mist while:
- producing chromate pigments and powders; chromic acid; chromium catalysts, dyes, and coatings
- working near chrome electroplating
- welding and hotworking stainless steel, high chrome alloys and chrome-coated metal
- applying and removing chromate-containing paints and other surface coatings.

Breathing small amounts of hexavalent chromium even for long periods does not cause respiratory tract irritation in most people.

Some employees become allergic to hexavalent chromium so that inhaling chromate compounds can cause asthma symptoms such as wheezing and shortness of breath.

How hexavalent chromium affects the skin

Some employees can also develop an allergic skin reaction, called allergic contact dermatitis. This occurs from handling liquids or solids containing hexavalent chromium. Once an employee becomes allergic, brief skin contact causes swelling and a red, itchy rash that becomes crusty and thickened with prolonged exposure. Allergic contact dermatitis is long-lasting and more severe with repeated skin contact.

Direct skin contact with hexavalent chromium can cause a non-allergic skin irritation. Contact with non-intact skin can also lead to chrome ulcers. These are small crusted skin sores with a rounded border. They heal slowly and leave scars.
# MATERIAL SAFETY DATA SHEET

## PRODUCT IDENTIFICATION

PROJECT 76+ TYPE 303 STAINLESS

## HAZARDOUS INGREDIENTS

<table>
<thead>
<tr>
<th>INGREDIENTS/CAS#</th>
<th>%</th>
<th>PEL (PERMISSIBLE EXPOSURE LIMITS), TLV (THRESHOLD LIMIT VALUES) 8 HOUR TIME WEIGHTED AVERAGES, C (CEILING)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRON</td>
<td>.1309-37-1</td>
<td>68.20 &lt;10 mg/m³, 0.5 mg/m³</td>
</tr>
<tr>
<td>CHROMIUM</td>
<td>7440-46-8</td>
<td>17.50 &lt;0.5 mg/m³, 0.1 mg/m³</td>
</tr>
<tr>
<td>NICKEL</td>
<td>7440-02-0</td>
<td>9.20 &lt;1 mg/m³, 0.2 mg/m³</td>
</tr>
<tr>
<td>MANGANESE</td>
<td>7439-96-5</td>
<td>1.90 &lt;0.5 mg/m³, C</td>
</tr>
<tr>
<td>COPPER</td>
<td>7440-50-8</td>
<td>.90 &lt;0.2 mg/m³, 1 mg/m³ (FUME)</td>
</tr>
<tr>
<td>COBALT</td>
<td>7440-48-4</td>
<td>.60 &lt;0.1 mg/m³, 0.1 mg/m³ (FUME)</td>
</tr>
<tr>
<td>MOLYBDENUM</td>
<td>7439-98-7</td>
<td>.50 &lt;5 mg/m³, 0.2 mg/m³ (INSOL)</td>
</tr>
</tbody>
</table>

## CHROMIUM

The toxicity of chromium is dependent on its oxidation state. Chromium metal is relatively non-toxic. If metal is heated to high temperatures, as in welding, fumes produced may be toxic to the lungs. Under high temperatures, hexavalent chromium may be produced if in the insoluble form it is designated a confirmed human carcinogen. Other health effects include nasal irritation and possible kidney and liver damage. Chromite dust may also cause skin ulceration, dermatitis and allergic skin reactions.
SCAQMD Rule 1430

What we know

– Per OSHA and other sources, Cr\(^0\) can convert to Cr\(^{+6}\) under high temperature conditions (Known as of July 2006)
– Limited testing at Houghton confirms OSHA Fact Sheet
– Paper will be presented at STLE Annual meeting May 2017

What we do not know

– Cut off conversion temperature (2200\(^\circ\)F ??)
– Alloy sensitivity
– Permanence of Conversion Cr\(^6\) reverts to Cr\(^{+3}\) to Cr\(^0\) ??
– Efficiency of conversion (Parts per Trillion or % by Weight)
SCAQMD Rule 1430

Impact

– Now - All Forge Facilities in SCAQMD
– Next - All processes in Forge Plants
  • Furnaces
  • Forge Process
  • Post deburring operation
SCAQMD Rule 1430

Impact for ILMA Members

– Employee safety in open (now closed) machining operations where high chrome alloys are present may require better PPE

– Possible Neighbor Concerns

– Possible Shift (not loss) of Business to other Countries or Areas from SCAQMD

– Questions from end users – Global issue, not just SCAQMD as word gets out
Chlorinated Paraffin Global Regulatory Update

For ILMA Metalworking Fluids Committee Meeting
Active Regulatory Areas

- UN: Stockholm Convention
- Korea
- European Union
- Canada
- United States
Stockholm Convention

• Persistent Organic Pollutant (POP)
• SCCP under consideration for 10 years
  – C10-13 chloroalkane, >48% Cl by wt.
• Repeated attempts to list SCCP as a POP have failed.
• Recently agreed to a risk management evaluation in September 2016 that may pave the way for its ultimate listing, though China and Russia continue to raise objections.
• There seems to be general agreement around a 1% cut-off for risk management.
• Not expected to have an impact on CPs manufactured in North America or Europe.
Korea

• Korea (South) recently established a chemical evaluation and registration regulation along the lines of REACH (K-REACH)

• K-REACH is focused on priority substances.

• MCCP is among several hundred priority substances slated for registration under K-REACH in 2018.

• MCCP REACH Consortium (Europe) working with K-REACH group on data sharing.
  – Existing database should be adequate for K-REACH.
Europe

- REACH is main regulatory activity impacting CPs in Europe, though WFD and RoHS also active.
- SCCP no longer manufactured in EU and there are no active registrations under REACH.
- MCCP and LCCP are actively registered under REACH by numerous companies.
  - MCCP: CAS 85535-85-9; EC 287-477-0
  - LCCP: CAS 63449-39-8; EC 264-150-0
- MCCP currently undergoing substance evaluation with additional testing on environmental fate.
Europe – MCCP Testing

• Based on preliminary substance evaluation, ECHA mandated additional persistence and bioaccumulation of select “components” of MCCP

• ECHA accepts that MCCP up to 50% Cl by wt. is readily biodegradable (therefore not a PBT).

• This testing focused on select carbon numbers (C14 and C15) in the 50-60% Cl by wt. range.
  – OECD 308 – sediment biodegradation studies
  – OECD 305 – fish bioaccumulation studies

• Analytical chemistry remains a challenge for fate testing of MCCP, though new techniques have recently been developed by specialized labs.

• Testing to be completed by summer 2018.
Canada

- Regulatory focus on “chloroalkanes” by carbon number, not on specific CAS numbers/substances.
- C10-20 chloroalkanes were added to CEPA Schedule 1 (“CEPA Toxic”).
- C10-C13 chloroalkanes are prohibited.
- C14-C20 chloroalkanes are subject to risk management; may be done through a combination of federal and provincial programs.
- Have recently had preliminary discussions with Canada about the addition of new CP CAS numbers to the DSL; process is underway.
U.S.

- PMN submitters met jointly with EPA on April 12, 2017. At this meeting, EPA stated that it intends to approval all outstanding CP PMNs and subject these to TSCA 5(e) consent orders (COs).

- The COs are to include provisions for additional environmental testing.
  - PMN submitters have not yet seen the COs.

- EPA will create a SNUR mirroring the COs for suppliers who didn’t sign them (e.g. foreign suppliers that did not submit PMNs).
• Once COs are signed, PMN submitters will be filing Notices of Commencement (NOC).
• The receipt of NOCs will prompt EPA to add the substances (and CAS numbers) to the TSCA Inventory.
• CP users in the U.S. may see updated literature/SDS from suppliers with new substance names and CAS numbers for some products.
U.S. – CP Testing

• vLCCP testing is underway.
• New testing on other CP products will likely start later in 2017.
• Much of this testing is lengthy and we won’t have information on the results for several years or more.
Thank You!

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Canada Assessment – Glycol Ethers

John K. Howell, Ph.D., GHS Resources Inc.
Ethylene Glycol Ethers Group

What are they?

- There are seven substances in the Ethylene Glycol Ethers Group.
- These substances are industrial chemicals. They are not expected to occur naturally in the environment.

How are they used?

- In Canada, the substances assessed in the Ethylene Glycol Ethers Group are used in cosmetics and non-prescription drugs, paint and coating products, air fresheners, household cleaning products, as well as in adhesives, batteries and textiles.
- Based on the most recent data, all seven substances are imported into Canada; in addition, four of the seven substances are manufactured in Canada.

Why is the Government of Canada assessing them?

- Substances in the Ethylene Glycol Ethers Group were identified as priorities for assessment through the categorization of substances on the Domestic Substances List (DSL) and/or they were associated with human health concerns.
- They are being assessed under the Chemicals Management Plan for potential risks to the environment and to human health.
- Two additional substances (CAS RNs 111-96-6 and 112-49-2) were initially identified as belonging to the Ethylene Glycol Ethers Group; however, they are no longer being assessed as part of this group. Instead, these two substances were considered in the Ecological Risk Classification of Organic Substances.
### Substances Reviewed

<table>
<thead>
<tr>
<th>CAS RN</th>
<th>Common Name</th>
<th>DSL Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>110-71-4</td>
<td>Monoglyme [Ethylene glycol dimethyl ether]</td>
<td>Ethane, 1,2-Dimethoxy-</td>
</tr>
<tr>
<td>111-46-6</td>
<td>Diethylene glycol</td>
<td>Ethanol, 2,2'-oxybis-</td>
</tr>
<tr>
<td>111-90-0</td>
<td>Diethylene glycol monoethyl ether</td>
<td>Ethanol, 2-(2-ethoxyethoxy)-</td>
</tr>
<tr>
<td>112-07-2</td>
<td>Ethylene glycol monobutyl ether acetate</td>
<td>Ethanol, 2-butoxy-, acetate</td>
</tr>
<tr>
<td>112-27-6</td>
<td>Triethylene glycol</td>
<td>Ethanol, 2,2'-[1,2-ethanediyl]bis(oxy)</td>
</tr>
<tr>
<td>112-34-5</td>
<td>Diethylene glycol monoethyl ether</td>
<td>Ethanol, 2-(2-butoxyethoxy)-</td>
</tr>
<tr>
<td>112-60-7</td>
<td>Tetraethylene glycol</td>
<td>Ethanol, 2,2'-[oxybis(2,1-ethanediyl)oxy]bis-</td>
</tr>
</tbody>
</table>
Screening Assessment Results

• Based on the results of the screening assessment, the Government of Canada is proposing that these seven substances are not entering the environment at levels that constitute a danger to the environment.
• The government is also proposing that these substances are not harmful to human health at current levels of exposure.
• The Government of Canada is therefore also proposing that these five substances are not harmful to human health at current levels of exposure.

The Government of Canada published the Draft Screening Assessment for the Ethylene Glycol Ethers Group on March 4, 2017. This publication is associated with a 60-day public comment period ending on May 3, 2017.
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Boric Acid Update

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

• Canada update
• Regulatory Status
  – European Union SVHC
  – US OSHA Classification
• Reproductive Toxicity
• Boric Acid Esters
Canada: Boric Acid Update

- July 23, 2016, Environment Canada published Draft Boric Acid Screening Assessment initiating 60-day comment period
  - Includes boric acid, borax, sodium tetraborate but not boric acid amides
  - “The draft screening assessment proposes to conclude that boric acid, its salts and its precursors are harmful to the environment as set out in section 64 (a) of CEPA 1999. It also proposes to conclude that boric acid, its salts and its precursors are harmful to human health as set out in section 64 (c) of CEPA 1999.”
- Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before July, 2017
Boric Acid – Regulatory Status

• Boric acid and several of its sodium salts (e.g., borax, disodium tetraborate, etc.): included on list EU of Substances of Very High Concern (SVHC), 06/10/2017
  – Classification: Reproductive Toxin, Cat 1B(H360), Signal word: Danger
    • Hazard Statements, May damage fertility. May damage the unborn child
    • Within EU, specific concentration limits (SCL) apply, e.g., a mixture needs to contain 5.5% or more boric acid (equiv. to 1% boron) before the mixture itself must be classified
    • Recently recommended for inclusion on Annex XIV, but not yet so listed
  
• U.S, a mixture containing 0.1% or more boric acid is classified as Cat 1 reproductive toxin: Danger, May damage fertility or the unborn child
Boric Acid – Reproductive Toxicity

• Scialli, et al., 2010: Authors did not find any clear evidence of male reproductive effects attributable to boron with exposures to Chinese miners of between 11 – 125 mg/day (equivalent to 70 – 850 mg borate/day)
  – An 8-hour exposure to 5 mg/l mist containing 0.5% borate (assuming inhalation of 10 m³ air) gives maximum exposure of 0.25 mg/day

• Ball and Harrass, 2013: Authors, using weight of evidence approach, conclude that it is improbable that boric acid will cause reproductive or developmental effects in humans:
  – Differences between gestation periods as well as mechanistic differences between laboratory animals and humans suggest the likelihood of similar effects in humans is low
  – Mechanism of boric acid is similar to aspirin, a widely used drug known to cause developmental effects in rodents, but not shown to cause developmental effects in humans in controlled studies

Ball, R. Wayne and Harrass, Michael, Rio Tinto Minerals, Greenwood Village, CO., Society of Toxicology, 2013, Poster
Boric Acid Esters

• Compare CAS 68586-07-2, boric acid, compd. with 2-aminoethanol (1:1), which is a salt, with CAS 68130-12-1, boric acid, 2-aminoethyl ester.

• UKLA reports (July, 2015) that the
  – “complex reaction product of boric acid and ethanolamine is not classified for reproductive hazard today due to an absence of test data...registrants have submitted a test plan as part of their REACH registration and are committed to performing reproductive toxicity testing of this substance.”

• Published reports indicate some commercial borate esters do not hydrolyze to re-form boric acid

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1 – Anderson, S., Does Boric Acid Have a Future in Metalworking Fluids, Tribology & Lubrication Technology, November, 2012, pp. 40 – 42,
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MWF Studies on Autoworkers

John K. Howell, Ph.D., GHS Resources Inc.
Papers Reviewed


Papers Reviewed


Papers Reviewed


• “Deficiencies in Air Filtering Cause Respiratory Symptoms in Machining Shops,” press release by the Finnish Institute of Occupational Health, Helsinki, Finland, 9 November, 2016

• Centers for Disease Control, National Institute of Occupational Safety and Health, Health Hazard Evaluations, “Evaluation of Metalworking Fluid Exposure and Dermatitis at a Gun Barrel Manufacturing Facility,” April, 2017
Shrestha, et al., Renal Cell Carcinoma (RCC)

- GM-UAW cohort follow-up study
  - 33,421 individuals followed 1985 through 2009
  - Cohort linked to Michigan Cancer Registry
  - RCC analyzed in relation to each specific MWF (straight, soluble, synthetic) and then all three types pooled into a single MWF variable, with 15 year lag
  - 135 incident cases
  - Linear increase in log-Cox Proportional Hazards Regression (HR) observed for all three MWF types and for total MWF exposure: at the mean of total MWF exposure (18.80 mg/m³-yr), estimated HR was 1.11 (95% CI 1.04, 1.19)
  - Author’s conclusion: results provide evidence of dose-dependent between MWF exposure and RCC.
    - Trend for white males steeper than for black males
    - Synthetic MWF yielded strongest dose-response relationship
Picciotto, et al., Straight Metalworking Fluids

• GM-UAW cohort follow-up study
  – 38,666 workers at 3 plants hired between 1938-1982 and who worked > 3 years
  – Compared observed survival times vs. what would have happened if nobody had been exposed:
  – Authors:
    • “estimated that banning straight metalworking fluids could have saved a total of 8,648...person-years of life among those who died during follow-up and 4,334...person-years of life among those who died from IHD” [ischemic heart disease]
    • ‘On average, 3.04...years of life could have been saved for each exposed worker who died from ischemic heart disease”
    • Results “provide evidence supporting hypothesis of a detrimental relationship between straight metalworking fluids and mortality, particularly from ischemic heart disease...”
Picciotto, et al., Hypothetical Exposure Limits

• GM-UAW cohort follow-up study (same cohort as previous study). Authors report that:
  – “if straight metalworking fluids had been banned, workers who were ever exposed and who died of cardiovascular disease would have lived 1.58...years longer”
  – “on average, IHD deaths would have happened 2.77...years later,”
  – “those who died from AMI [acute myocardial infarction] would have lived 3.13...years longer,” and
  – “Deaths from cerebrovascular disease would have occurred a mean of 3.19...years later.
  – “…reducing he occupational exposure limit for straight metalworking fluids to 0.01 mg/m³ would have saved 2,000 life-years in this cohort who died of cardiovascular disease.”
Garcia, et al., Healthy Worker Survivor Effect

• GM-UAW cohort follow-up study (31,485 workers followed for cancer incidence from 1985 to 1994)
• Healthy worker survivor effect (HWSE) depends on three conditions:
  1. Leaving work predicts future exposure
  2. Leaving work is associated with disease outcome, and
  3. Prior exposure increases probability of leaving work.
• Results:
  – HR for leaving work as a predictor for all cancers combined and prostate cancer was null but elevated for lung and colorectal cancers among men
  – Condition (2) more clearly satisfied for all cancer outcomes when leaving work occurred by age 50
  – Higher exposures to all three MWF types were associated with increased rates of leaving work (condition (3)) except for straight MWF among women
Condition 2: leaving working and cancer incidence.

Erika Garcia et al. Occup Environ Med 2017;74:294-300
Koller et al., Switzerland; Finnish Inst. Occ. Health

• Koller, et al., results:
  – 90th percentile for MWF air concentration was 8.1 mg(aerosol + vapor)/m$^3$ and 0.9 mg aerosol/m$^3$ (inhalable fraction)
  – 1,280 cases of skin disease and 96 cases of respiratory disease observed
  – Authors note that “this is the first investigation describing exposure to and diseases due to MWF in Switzerland over a timeframe of 10 years. In general, working conditions in the companies of this investigation were acceptable.”

• Finnish Institute of Occupational Health press release 11/09/2016:
  – Study “detected deficiencies in local exhaust ventilation air filtering...is not capable of removing gaseous pollutants generated by metalworking fluid... workers exhibit symptoms, such as rhinitis, coughing, ocular symptoms, shortness of breath, asthma and other respiratory symptoms.”
NIOSH HHE

• NIOSH investigators found a statistically significant association between skin exposure to coolant and work-related dermatitis. Some employees reported work-related, asthma-like symptoms. Employees with work-related respiratory symptoms were exposed to airborne metal working fluid (MWF) levels known to cause or exacerbate respiratory symptoms. We recommended limiting skin and respiratory exposure to MWF by improving MWF mist control, changing manual handling practices, and improving access to and consistent use of gloves.
American Chemistry Council

Initiative to Reform the International Agency for Research on Cancer
IARC

• ACC concerned about scientific and process deficiencies of IARC and the resulting policy decisions predicated on its work (E.g., Prop 65 listings)

• Website notes “Rather than informing consumers of carcinogenic risks in realistic exposure scenarios, IARC considers only a substance’s hazard – whether the substance could cause cancer in humans under any circumstances, in most cases at exposure levels far beyond what is typical.”

• More info on website: http://campaignforaccuracyinpublichealthresearch.com
Chemical Salts
New Business

1. Canadian Biocide Issue
   Richard Rotherham – Troy Corporation

2. NIOSH Control Banding
   John Howell, Ph.D.
   GHS Resources
PROPOSED RESTRICTION OF CIT/MIT BIOCIDE USE FOR MWF’S BY PMRA, HEALTH CANADA
PMRA, HEALTH CANADA IS REQUESTING ALL REGISTRANTS OF CIT/MIT BIOCIDES IN CANADA TO AMEND LABELS FOR A LOWER MAXIMUM USE FOR:

ADHESIVES, PAINTS/COATINGS, CONSTRUCTION PRODUCTS, COLORANTS, LATTICES, MWF’S ETC.

FOR MWF’S PROPOSED MAXIMUM USE LEVEL IS 8 PPM OF ACTIVE (CIT/MIT)

- EQUIVALENT TO USING 0.05% OF A 1.5% ACTIVE PRODUCT
IMPORTANT TO NOTE THAT THERE ARE FAR FEWER REGISTERED BIOCIDES AVAILABLE FOR USE IN MWF’s IN CANADA THAN ARE US EPA REGISTERED.

- FOR MWF CONCENTRATES AND

- FOR TANKSIDE USE
SO IT’S ESSENTIAL THAT THE TOOLS AVAILABLE ARE ABLE TO BE USED AT EFFECTIVE LEVELS.
AMERICAN CHEMISTRY COUNCIL ISOTHIAZOLINONE TASK FORCE FORMED TO WORK WITH PMRA TO ADDRESS THEIR ASSESSMENT.

CONFERENCE CALL WITH PMRA HELD APRIL 10, 2017.
DURING CONFERENCE CALL, TASK FORCE MADE PRESENTATIONS ON:

- KEY BENEFITS OF CIT/MIT
- ADDITIONAL INFORMATION ON TOXICITY AND ASSESSMENT CONSIDERATIONS
- IMPACT OF IMPLEMENTING LOWER USE LEVELS
Request for Delay in Label Amendments

- Impact is large both for registrants and customers/end users
- Additional consideration is requested for conclusions regarding use levels
PMRA, HEALTH CANADA SIGNALLED THAT THEY WERE OPEN TO HEARING FROM END-USERS REGARDING EFFICACY CONCERNS.

WE BELIEVE THAT TO IMPACT THE FINAL DECISION(s) RE USE LEVELS, ANY FEEDBACK NEEDS TO BE RECEIVED BY PMRA BY THE END OF THIS MONTH (APRIL 2017).
I REQUEST THAT THE MWF COMMITTEE ASK ILMA TO SEND A LETTER TO PMRA, HEALTH CANADA EXPRESSING MEMBERS CONCERNS.

LETTERS FROM INDIVIDUAL MEMBER COMPANIES WOULD ALSO BE VALUABLE SUPPORT.
LETTERS SHOULD IDENTIFY / ADDRESS:

- MWF INDUSTRY EXPERIENCE WITH CIT/MIT OVER MANY YEARS OF USE, IS THAT THE PROPOSED USE LEVEL OF 8 PPM ACTIVE CIT/MIT IS INEFFECTIVE IN CONTROLLING CONTAMINATION IN MWF’S.

- REQUEST PMRA, HEALTH CANADA TO UPHOLD THE EXISTING APPROVED USE LEVELS FOR MWF’S.

- NOTE THAT EXISTING USE LEVELS HAVE NOT BEEN ASSOCIATED WITH ANY ADVERSE HEALTH EFFECTS TO WORKERS TO THE BEST KNOWLEDGE OF THE WRITER.
LETTERS SHOULD BE SENT TO:

Peter Brander, PhD, Chief Registrar  peter.brander@canada.ca

Margherita Conti, PhD, Director General, Value Assessment & Re-evaluation Directorate  margherita.conti@canada.ca

Peter Chan, PhD, Director General, Health Evaluation Directorate  peter.chan@canada.ca

Yadvinder Bhuller, Director, Health Effects Division 1  Yadvinder.bhuller@canada.ca
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario
K1A 0K9
THANK YOU!

ANY QUESTIONS??
ILMA 2017 Management Forum
MWF Committee

NIOSH Control Banding

John K. Howell, Ph.D., GHS Resources Inc.
Control Banding Draft Criteria Document

• NIOSH published 141 page draft Criteria Document on March 8, 2017:
  The NIOSH Occupational Exposure Banding Process:
  Guidance for the Evaluation of Chemical Hazards

• Public hearing: Tuesday, May 23, 2017, Cincinnati, OH
• Comments due: June 13, 2017
The National Institute for Occupational Safety and Health (NIOSH)

The NIOSH Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards

NIOSH Docket Number 290, CDC-2017-0028

March 2017

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of a draft Current Intelligence Bulletin entitled The NIOSH Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards for public comment. NIOSH is seeking comments on the draft document and plans to have a public meeting to discuss the document.

To view the notice and related materials, visit https://www.regulations.gov and enter CDC-2017-0028 in the search field and click “Search”.

The Public Meeting will be held on Tuesday, May 23, 2017 from 9 a.m.-3 p.m., Eastern Time. Please note that public comments may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the meeting at the start time listed.

Reference Documents

- Federal Register Notice: Federal Register Notice Correction to Meeting Date
DRAFT

Table 1-1: Airborne concentration ranges associated with occupational exposure bands

<table>
<thead>
<tr>
<th>Occupational Exposure Band</th>
<th>Airborne Target Range for Particulate Concentration (mg/m³)</th>
<th>Airborne Target Range for Gas or Vapor Concentration (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>&gt;10 mg/m³</td>
<td>&gt;100 ppm</td>
</tr>
<tr>
<td>B</td>
<td>&gt;1 to 10 mg/m³</td>
<td>&gt;10 to 100 ppm</td>
</tr>
<tr>
<td>C</td>
<td>&gt;0.1 to 1 mg/m³</td>
<td>&gt;1 to 10 ppm</td>
</tr>
<tr>
<td>D</td>
<td>&gt;0.01 to 0.1 mg/m³</td>
<td>&gt;0.1 to 1 ppm</td>
</tr>
<tr>
<td>E</td>
<td>≤0.01 mg/m³</td>
<td>≤0.1 ppm</td>
</tr>
</tbody>
</table>
Figure 2-1: Tier 1 overview for quickly banding chemicals in Tier 1.

1. Chemical of interest has no OEL
2. Locate GHS hazard codes and categories in recommended databases
3. Compare hazard codes and categories with NIOSH criteria for each health endpoint
4. Assign band for each relevant health endpoint based on criteria
5. Assign a Tier 1 OEB for the chemical based on most protective endpoint band
Figure 3-1: Overview of Tier 2 process

1. **Begin Tier 2 process**
2. **Search recommended databases for toxicity information**
3. **Compare qualitative and quantitative data to NIOSH Tier 2 banding criteria**
4. **Assign band for each health endpoint based on NIOSH tier 2 banding criteria**
5. **Assign a Tier 2 OEB for the chemical based on most protective endpoint band**