

Chlorinated Paraffins: Regulatory Issues

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What are Chlorinated Paraffins?

- CP's are a complex mixture of polychlorinated n-alkanes. Hydrocarbon can be paraffin or alpha olefin.
- Introduced in the 1930's.
- Global capacity of CP's is over 2000 ktes (4 billion lbs), China and India and largest producers by far.
- Used in Plastics, Metal Working Fluids, Paints, Adhesives, and Rubber.

- Classified according to chain length and chlorine content:
 - Chain length of C_{14} to C_{30}
 - % chlorine from 35 to > 70% by weight
- Two common feedstocks in N.A. and Europe are:
 - Mid chain (C_{14-17})
 - Long chain (C_{18-30})
- Chinese CP often have wider ranges (e.g. C_{10-20})

Applications for CP's

- **Flame Retardants** for rubber, plastics, industrial coatings, sealants, adhesives and textiles.
- **Plasticizers** for PVC.
- **Additive** for paint, coatings, and textiles to impart water repellency and chemical resistance.
- **Extreme pressure additive** for metal working fluids.

REGULATORY

Historical Timeline

- 1976 TSCA legislation passed by Congress.
- 1976 CP's first identified for testing.
 - Four representative compounds were selected for the testing:
 - SCCP; 58% Cl wt.
 - MCCP; 52% Cl wt.
 - LCCP 43% Cl wt.
 - LCCP; 70% Cl wt.
- 1985 Testing completed
 - Limited mammalian toxicity generally observed, though some concerns noted in SCCP cancer study (later determined to be a limited importance for humans).
 - Effects seen in some aquatic studies.
 - EPA conducts risk management (RM) review of CPs and determined that SCCP was the most toxic to aquatic life and that the greatest potential risk is from water soluble metalworking fluids.
 - EPA ultimately decides to take no official action on CPs under TSCA, though does require the reporting of C10-C13 CP/CA on the annual Toxic Release Inventory (TRI).

Historical Timeline

- 2009 EPA began posting chemical action plans (CAPs) for priority substances for review.
 - SCCP was among the first
 - SCCP 2009 CAP mentions concerns that SCCP is a persistent, bio accumulative, and toxic (PBT) substance and discusses the possibility of actions under TSCA section 6a to ban or restrict its manufacture, import, processing or distribution, export, and use.
- 2009 EPA issues subpoenas (formal request for information) to the manufacturers and importers of CPs in the U.S. Based on the responses to the subpoenas, EPA takes the position that ALL current CP products on the market in the U.S. are not adequately listed on the TSCA Inventory.
- EPA issues Notice of Violation (NOV) to main CP manufacturer and importer.

Historical Timeline

- 2010 To resolve TSCA Inventory concerns, Dover and INEOS Chlor negotiate consent decrees with EPA.
 - Resolves previous Notice of Violation (NOV) regarding TSCA Inventory.
 - No future production/import of SCCPSubmission of PMNs for current MCCP and LCCP products
 - Allows for continued production/import of MCCP and LCCP, minimizing the impact to downstream businesses and operations.
- 2012 EPA releases a prioritization approach for screening chemicals for further review and possible regulation under TSCA. The release includes over 80 substances that EPA is calling TSCA Work Plan chemicals. MCCP and LCCP are on the list.
- 2012 CP suppliers submit required Pre-manufacture Notices (PMN) for all MCCP and LCCP/vLCCP substances, initiating (new chemical) review process.

Historical Timeline

- 2013 – EPA adds several vLCCP (>C21) substances to the TSCA Inventory and proposes SNURs on these substances.
- 2014 (December) – EPA provides (confidential) Draft Risk Assessments for MCCP and LCCP to just the individual PMN submitters.
- 2015 (January) EPA sends letters to PMN submitters indicating that based on their concerns from the draft risk assessment MCCP and LCCP can no longer be produced past May 31, 2016.
- 2015 (September) EPA pushes the cessation date out to mid-2017 based on industry pressure.
- 2015 (December) EPA Publishes Federal Register Notice of Risk Assessments on MCCP/LCCP. Call for comments.

Risk Assessment Conclusions

- EPA indicated concerns for risk to environmental organisms, persistence and bioaccumulation potential in the draft MCCP/LCCP risk assessments.
- EPA did not find a human health concern.
- EPA acknowledges exposure estimates are highly conservative as they attempted to develop “worst-case” assessment.
- EPA often did not use the information provided in the PMNs for how substances are used and disposed but instead made assumptions on use to maximize releases to water.

Process Concerns with EPA Activities on MCCP and LCCP

- PMN process means only PMN submitters and EPA have access to documents/risk assessments.
 - CPIA/ILMA involvement only due to PMN submitters sharing information.
- Risk assessments say “draft” in title and “draft and deliberative” in header, though EPA only allowed a minimal (~30 day) review and comment period (and only after being pressed).
 - Initial comments limited to PMN submitters and CPIA.
 - CPIA comments are available to share; PMN submissions and related documents are not public.

Process Concerns with EPA Activities on MCCP and LCCP

- EPA issued PMN action letters in January 2015 only a few days after PMN submitters and CPIA submitted comments on risk assessment.
- Not clear when or if EPA will have a public comment period and external peer-review of the risk assessments, though both are listed on EPA's TSCA Workplan website.
 - **Update: EPA published the mccp/lccp risk assessments and issued a call for comments by March 22, 2016**

Concerns with Risk Assessments

- It is not clear which data EPA relied upon for their conclusions and why those data were selected. MCCCP has a large database so linking conclusions with specific studies is necessary for transparency.
- Industry has provided considerable data and analyses that indicate strong biodegradation potential and a lack of bioaccumulation; not clear how or if these data were reviewed/considered.
 - Bioaccumulation reviews by independent experts are published or otherwise available to share. Papers were provided to EPA in mid-2014 and again in 2015

Concerns with Risk Assessments (Con't)

- Modeled exposures used release assumptions that are highly questionable, in many cases perhaps not even permitted under existing regulations (e.g NPDES permits restrict discharges).
 - EPA used their own numbers not what PMN submitters provided.
- A recent expert review of the monitoring data provided in the EPA assessment shows levels in the U.S. and Canada are below the concentrations of concern. Contradicting EPA's conclusions from these same data.

Issues with the current EPA Process

- CP's have been manufactured and used for ~70 years.
- By concluding the existing TSCA Inventory nomenclature for CPs is inadequate, EPA is now regulating these substances as “new” chemicals. New chemicals reviews are much more conservative and without the benefit of public comment and peer-review.
- The PMN process does not allow for stakeholder or impacted industry comment or involvement.

Issues with the current EPA Process (Con't)

- Data submitted on biodegradability, environmental release, etc. not given obvious consideration or discounted. Dover believes there is adequate information to support that MCCP and LCCP are not PBT substances.
 - LCCP recently (Oct. 2009) reviewed by OECD, which includes EPA and Environment Canada. It concluded LCCP has a low order of toxicity and is not a PBT.
 - MCCP REACH registration, completed in late 2010 and utilizing new data, concludes MCCP is not a PBT.

Impact of EPA Action

- Proposing an unrealistic ban on production after mid-2017 allows no time for industry to adjust – will affect numerous industries / employment.
- Creates further incentive to shift production overseas.
- Action will have little impact on the global production as Asia already dominates.

Current Activities and Next Steps

Current Activities

- CP suppliers are also continuing to analyze EPA's environmental fate (persistence and bioaccumulation) assessment and getting outside expert opinions.
- EPA has proposed a series of additional studies, though there are technical and feasibility issues with conducting these studies. Other studies may be feasible and appropriate, though developing that testing plan would require involvement of outside experts and labs.
 - EPA indicated at the February 2015 meeting that additional time would not be provided even if new testing is agreed to.

DoD Involvement

- CPIA/ILMA has engaged the DoD given the significant impact on the defense products supply chain.
- CPIA and ILMA had webinar with DoD on April 9, 2015.
- DoD has indicated a strong level of interest and may be willing to support industry's efforts to extend deadline and improve risk assessments.
- Additional time from EPA is likely to occur only if “critical uses” are identified by DoD and other influential parties.
 - DoD sent letter to EPA June 5, 2015. No response as of September 25, 2015.

Congressional Involvement

- June 2/3, 2015, ILMA and PMN submitters met with congressional representatives in DC to discuss the current MCCP/LCCP situation.
- Bob Gibbs – R, 7th Congressional district of Ohio, expressed keen interest in supporting this industry.
- A letter was sent to Gina McCarthy, head of EPA, and was signed by 12 congressmen beginning of August
- Both Senators from Ohio, Rob Portman (R) and Sherrod Brown (D) have expressed support and may send senatorial letters to EPA.

Industry Involvement

- Chlorinated Paraffins Industry Association (CPIA)
 - At least 6 letters sent on exposure, environmental fate and LCCP review
- Independent Lubricant Manufacturers Association (ILMA)
 - Met with EPA June 3, 2015
 - Sent letters on critical uses, timing and cost of conversion June 10, July 24, September 10, 2015

Industry Involvement (Con't)

- American Coatings Association (ACA)
 - Sent letter to EPA September 17, 2015 expressing concerns with the process being used and importance of MCCP's to the industry.
- International Fasteners Institute (IFI)
 - Critical use in bolts and fasteners for aviation (DoD)
 - Sent letter to EPA May 26, 2015
- American Wire Producers Association (AWPA)
 - Letter sent August 19. 2015

Industry Involvement (Con't)

- American Coatings Association (ACA)
 - Letter sent September 17, 2015
- Adhesives and Sealants Council (ASC)
 - Letter sent September 16, 2015
- American Chemistry Council (ACC)
 - Letter sent September 22, 2015
 - Letter sent to Office of Management and Budget October 2, 2016 emphasizing the economic impact of a ban.

EPA Publishes Federal Register Notice of Risk Assessments on MCCP/LCCP

- As a result of joint efforts, EPA published a Federal Register Notice on December 23, 2015 that contained the risk assessments and requested “new, available data” on MCCPs and LCCPs.
- Comments were requested to be received by March 23, 2016.

Comments Recieved

- Coalition of impacted trade associations including: the American Chemistry Council, the Chlorinated Paraffins Industry Association, the American Wire Producers Association, The Independent Lubricant Manufactures Association, the Industrial Fasteners Institute, the Center for the Polyurethane Industry, the Auto Alliance, the Global Automakers, the Vinyl Institute, the Aerospace Industry Association, the Adhesives and Sealants Council, and the Motor and Equipment Manufacturers Association.

Other Comments Submitted

- EPA received comments from stakeholders. Overall, the Agency received a total of 27 comments.
- Other notable submissions, in addition to comments filed from the Coalition's members, came from the Department of Defense, Boeing, Dow Chemical, 3M, the Auto Alliance, Global Automakers, and the Aerospace Industries Association.
- All comments submitted can be viewed at www.regulations.gov (docket ID number EPA-HQ-OPPT-2015-0789)

Coalition Comments

- Coalition comments concerns with EPA's overall regulatory approach, offered alternative paths forward, and questioned EPA's conclusions that MCCPs and LCCPs are persistent, bioaccumulative, and toxic (PBT).
- Additionally, the comments echoed the need for independent scientific peer review and that MCCPs and LCCPs should be reviewed as existing substances.

Congressional Letter Response

- The Members of Congress finally received a response from EPA regarding the letter that was sent in July 2015. It is fairly generic and sticks primarily to EPA's talking points that MCCPs and LCCPs are new chemicals and are being reviewed as such.
- It did indicate that the Agency “anticipates making a final decision on the PMNs after consideration of new data.”

Comments Were Submitted, Now What?

- No guarantee how EPA will proceed since virtually this entire process is unprecedented.
- In a recent conversation with EPA, they indicated that a technical review of the comments would take place this month and a report and possibly modified risk assessment would be issued in early June.

Next Steps

- Industry plans to work both independently and with the Coalition to push EPA to treat MCCPs and LCCPs as existing chemicals, to review the substances under its 2012 Work Plan, and to subject the Agency's conclusions to independent scientific peer review.
- There will also be continued efforts to move out the potential cessation date of MCCP/LCCP's beyond "mid-2017".