



MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

June 20, 2016

Mr. James Jones (7101M)
Assistant Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Request for Peer Review of Draft Risk Assessments on Medium-Chain Chlorinated Paraffins and Long-Chain Chlorinated Paraffins

Dear Jim:

The Environmental Protection Agency (EPA) has indicated an intention to require the cessation of manufacturing and importation of medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs), using its authority under section 5 of TSCA. Although EPA has published draft risk assessments (hereafter referred to as “the Risk Assessments”) and has taken public comments on them, the Risk Assessments have not been scheduled for external peer review. The American Chemistry Council (ACC) is reiterating its earlier request that the Risk Assessments be subject to external peer review.

The public comments on the Risk Assessments identified a number of significant errors and deficiencies. Indeed, many commenters urged EPA to ensure that the Risk Assessments receive external peer review. External peer review of the Risk Assessments is appropriate because they meet the triggers identified in the Office of Management and Budget’s (OMB) Final Information Quality Bulletin for Peer Review, and the errors and deficiencies in the Risk Assessments must be addressed. The procedural status of the MCCP/LCCP review under section 5 of TSCA is no reason to drop EPA’s previous plan for external review of the Risk Assessments.¹

¹ OMB, Final Information Quality Bulletin for Peer Review (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf, and EPA, Peer Review Handbook (4th ed., Oct. 2015), http://www2.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-4th_ed_091415_dummy_link.pdf



1. The Risk Assessments Meet the Triggers for External Peer Review in OMB's Guidance on Peer Review and EPA's Peer Review Handbook

ACC believes that EPA cannot rely on the Risk Assessments without subjecting them to independent scientific peer review. OMB guidance and EPA's own peer review policies and practices indicate that peer review is required.

EPA's Peer Review Handbook states that scientific information that the Agency "reasonably can determine will have or does have a clear and substantial impact on important policies or private sector decisions" is considered influential scientific information (ISI). A subset of ISI is a scientific assessment that "could have a potential impact of more than \$500 million in any year on either the public or private sector" or that "is novel, controversial, or precedent-setting, or has significant interagency interest" is considered a highly influential scientific assessment (HISA). All of the Agency's ISI/HISA should be peer reviewed unless they meet specified exemption criteria . . ."

The Risk Assessments clearly qualify as HISA and do not meet any exemption criteria.

The economic impact of a ban of MCCPs and LCCPs is expected to be much more than \$500 million per year. In 2011, the last year for which CDR data is available, manufacturers reported production or importation of 48 million pounds of chlorinated paraffins, most of which were MCCPs and LCCPs. Several commenters on the Risk Assessments explained that the impact of a ban on MCCPs and LCCPs. For example, the Independent Lubricant Manufacturers Association (ILMA) estimated that banning MCCPs and LCCPs would cost more than \$69 billion for its metalworking fluid (MWF) members, who represent just one downstream sector that would be impacted by a ban.² In its analysis, ILMA describes the mass-scale reformulation and testing that would be required at both MWF suppliers' facilities and at end-user customers' facilities. In addition, the Department of Defense commented that its suppliers rely on MCCPs and LCCPs to be able to produce important defense-related equipment – a clear indication that a ban would have national security implications.

Imposing a ban on MCCPs and LCCPs through the PMN process would clearly be an action that is "novel, controversial, or precedent-setting, or ha[ve] significant interagency interest." It would be highly unusual for the Agency to attempt to remove substances that have been in commerce for decades from the market using TSCA section 5, while simultaneously representing to the public that the Risk Assessments will be subject to peer review under the TSCA Work Plan. The controversial nature of EPA's proposed ban is readily apparent from the comments submitted to the docket and their attachments.

² See the ILMA comments in Docket EPA-HQ-OPPT-2015-0789, the docket for comments on the Risk Assessments. All subsequent references to comments refer to this docket.

The Risk Assessments are both ISI and HISA. EPA's Peer Review Handbook directs:

Per the OMB Peer Review Bulletin, all of the Agency's ISI/HISA should be peer reviewed unless they meet specified exemption criteria....³

The Peer Review Handbook further advises: "[w]hen in doubt about whether a work product merits peer review, decide to peer review it."⁴ Here, there is no doubt – external peer review is needed.

The Handbook indicates that one exemption criterion is whether the information is "disseminated in the course of an individual adjudication or permit proceeding (including a registration, approval, licensing or site-specific determination), unless the Agency determines that peer review is practical and appropriate and the influential information is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings."⁵ Although the Risk Assessments nominally relate to individual PMNs, the reality is that many entities well beyond the PMN submitters would be affected by any regulatory decision EPA makes based on the Risk Assessments. EPA included MCCPs and LCCPs in the TSCA Work Plan in clear recognition of the fact that they have been in commerce for decades and currently are used widely. EPA should not rely upon a regulatory fiction that only the PMN submitters would be affected by the Risk Assessments as a basis for failing to have external peer review.

2. A Section 5 Proceeding Provides no Basis to Drop EPA's External Peer Review Plan

Prior to 2015, EPA clearly planned to conduct external peer review for the Risk Assessments.

In 2012, EPA announced its TSCA Work Plan program to review priority chemical substances. MCCPs and LCCPs were included in the list of priority substances and were identified as being among the initial seven priority substances to be addressed.⁶ In 2013, EPA published a Peer Review Plan specifically for MCCPs and LCCPs.⁷ In 2014, EPA updated the list of TSCA Work Plan chemicals and continued to include MCCPs and LCCPs as priority substances for risk assessments under the TSCA Work Plan.⁸

In January 2015, however, EPA informed the MCCP and LCCP PMN submitters that it intended to pursue a ban on the manufacture and import of these substances using its authority under section 5 of TSCA. Today, EPA's Work Plan website indicates that it initiated its assessments in

³ Id.

⁴ Id. at 42.

⁵ Id. at 44.

⁶ See TSCA Work Plan Chemicals (June 2012), https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf.

⁷ The Peer Review Plan for MCCPs and LCCPs is still available on EPA's website at https://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=245552.

⁸ See TSCA Work Plan for Chemical Assessments: 2014 Update, https://www.epa.gov/sites/production/files/2015-01/documents/tsc_a_work_plan_chemicals_2014_update-final.pdf.

2012, but that the chemicals are being assessed under section 5.⁹ ACC and other stakeholders interpret this to mean that EPA does not plan to seek external peer review of the Risk Assessments.

ACC and others submitted extensive comments challenging EPA's use of section 5 in this matter. The mere fact that EPA has chosen to use section 5 is not a basis for EPA to forego external peer review for the Risk Assessments, however. Nothing in the section 5 process removes the need for an external peer review, particularly peer review that EPA has acknowledged and planned since 2012. We recognize that EPA typically does not use external peer review for PMN chemicals because EPA does not typically conduct risk assessments on PMN chemicals,¹⁰ but the MCCPs and LCCPs are far from the typical PMN scenario. Tens of millions of pounds of MCCPs and LCCPs are produced or imported annually, and tens of thousands of existing downstream processors and end users would be affected by EPA's actions under section 5.

3. Errors and Other Deficiencies in the Risk Assessments Must be Addressed

One important purpose of external peer review is to have experts in the relevant fields critically review the scientific basis for EPA's initial judgment regarding whether or not a chemical substance presents an unreasonable risk to health or the environment. If that scientific basis is flawed, EPA's judgment about the existence of an unreasonable risk is suspect.

As noted earlier, EPA sought public comment on the Risk Assessments, and many comments called for external peer review.¹¹

Several commenters, including DOD, the coalition of associations, CPIA, and The Dow Chemical Company noted that the Risk Assessments rely upon selective results and statements by others that support EPA's conclusions on environmental fate and effects. However, the Risk Assessments do not fully consider recent data and reviews that are contrary to EPA's conclusions, i.e., that support a determination that MCCPs and LCCPs are not persistent, bioaccumulative, and toxic substances. Given the wide range of data and results, EPA should subject the Risk Assessments to external expert peer review. We further note that the disparity in study quality and reliability suggest that EPA should apply a weight-of-the-evidence approach

⁹ See Assessments for TSCA Work Plan Chemicals, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsc/a/assessments-tsc-a-work-plan-chemicals>

¹⁰ See "EPA's Review Process for New Chemicals," <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsc/a/epas-review-process-new-chemicals>.

¹¹ On December 23, 2015, EPA requested public comments on the Risk Assessments, 80 Fed. Reg. 79886 (Dec. 23, 2015). Later, EPA extended the end of the comment period to March 23, 2016. 81 Fed. Reg. 8712 (Feb. 22, 2016). The docket includes comments from a coalition of trade associations, as well as individual company and trade association submissions. The Coalition includes the following organizations: ACC; ACC's Center for the Polyurethanes Industry; the Adhesive and Sealant Council; the American Wire Producers Association; the Chlorinated Paraffins Industry Association (CPIA); the Independent Lubricant Manufacturers Association (ILMA); the Industrial Fasteners Institute; the Motor and Equipment Manufacturers Association; and the Vinyl Institute.

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(as required under the Frank R. Lautenberg Chemical Safety for the 21st Century Act), which amends TSCA and is expected to be signed by President Obama in the near future.

Please let me know if we can provide any additional information on ACC's request.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Walls", written in a cursive style.

Michael P. Walls
Vice President
Regulatory & Technical Affairs

CC: Wendy Cleland-Hamnett
Jim Laity
Dominic Mancini
Tayyaba Zeb